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**OFFICE OF
INSPECTOR GENERAL**

External Quality Review of Dialysis Facilities

A Call For Greater Accountability



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EXECUTIVE SUMMARY

PURPOSE

To assess external mechanisms the Health Care Financing Administration relies upon to monitor the quality of care provided by dialysis facilities to Medicare beneficiaries with end-stage renal disease.

BACKGROUND

Importance of External Quality Review

Case files, performance data, and marketplace realities underscore the importance of external quality review of dialysis facilities. Case files reveal numerous instances of poor care. In one instance, we found that a patient received a drug overdose that resulted in prolonged bleeding and subsequent hospitalization. Performance data collected from dialysis facilities reveal that a substantial portion of patients do not achieve the outcomes recommended by clinical practice guidelines. Similarly, scientific studies suggest variation in the quality of care patients receive. Of particular note is one that revealed higher mortality rates at facilities providing lower doses of dialysis. Finally, marketplace pressures triggered by growth, consolidation, competition, and concerns about containing costs have caused service disruptions that can and have jeopardized patient care.

External Review Bodies

The Health Care Financing Administration (HCFA) relies upon two major entities to conduct external reviews of dialysis facilities: the End-Stage Renal Disease (ESRD) Networks established under the Social Security Act and the State survey agencies. HCFA contracts with the 18 Network organizations, which are governed primarily by renal professionals associated with facilities in the Network's region, to perform multiple functions, mostly oriented around collegial efforts to promote improvement in the quality of care and to respond to complaints lodged by patients, staff, and others. HCFA funds the State agencies, typically within departments of public health, to perform a more regulatory role: to conduct Medicare certification surveys of facilities and to investigate complaints, both in accordance with the Medicare Conditions for Coverage for dialysis facilities.

This Inquiry

In our inquiry, we relied on a rich variety of data sources. We reviewed and analyzed HCFA's database on State survey agencies; conducted a survey of all 18 Networks;

visited 5 Networks; held extensive telephone discussions with representatives of another 8; reviewed the complaint logs of 9 Networks; observed a State survey of a dialysis facility; interviewed staff at 5 State survey agencies; interviewed many stakeholders representing national organizations; and reviewed Federal documents and pertinent literature.

FINDINGS

The major strength of the external oversight system is the use of standardized performance measures to encourage improvements in the quality of care.

- ▶ HCFA-generated data show measurable improvements in clinical outcomes at the national and regional levels.
- ▶ Network quality improvement projects show improvements at the regional level and, in some cases, at the facility level.

Yet, that system of oversight falls short in several respects.

Standardized performance measures are rarely used to hold individual facilities accountable.

- ▶ HCFA does not require the collection of a core set of facility-specific clinical performance measures.
- ▶ Without such a set, Networks and States have limited means of identifying poorly performing facilities.
- ▶ A few Networks do collect facility-specific performance measures, but have limited authority to use them to correct poor performance.
- ▶ Networks and State agencies rarely share facility-specific data with one another.
- ▶ Facility-specific performance measures are not publicly disclosed.

The complaint systems serve as unreliable means for identifying and resolving quality-of-care concerns.

- ▶ Both patients and staff tend to be reluctant to lodge complaints because of concerns about the possible consequences for them.
- ▶ States and Networks conduct few investigations of complaints concerning the quality of care. In 1998, State survey agencies conducted about 250 on-site investigations; the Networks, about 35.

- ▶ States and Networks rarely conduct joint complaint investigations or share information on their own investigations.

Medicare certification surveys play a limited role in ensuring dialysis facilities meet minimum standards.

- ▶ The elapsed time between Medicare certification surveys conducted by the State survey agencies is increasing. In 1995, 20 percent of all facilities were not surveyed within 3 years; by 1998, that increased to 44 percent.
- ▶ Medicare Conditions for Coverage for dialysis facilities provide an inadequate foundation for accountability.
- ▶ State survey agencies have difficulty maintaining the expertise of surveyors, largely due to the infrequency of surveys.

Medical injuries are not systematically monitored. HCFA does not require the Networks, the State agencies, or facilities to identify and analyze medical injuries attributable to the care provided to the patient as opposed to the patient's underlying condition.

HCFA does little to hold the Networks and State survey agencies accountable for their effectiveness.

Minimal assessment of Networks' performance. Although HCFA receives regular information from Networks, it provides little substantive evaluation and feedback to them. HCFA does not hold Networks accountable for how facilities fare on performance measures.

Minimal assessment of State survey agencies' performance. HCFA has few means to evaluate the content or quality of the surveys the State agencies conduct on behalf of Medicare. HCFA no longer validates surveys and rarely observes surveys in action.

Minimal public disclosure. HCFA, the Networks, and the States disclose little information to the public on actions taken to protect dialysis patients.

RECOMMENDATIONS

Our review indicates that the external review system carried out on HCFA's behalf by the Networks and the State agencies has major shortcomings. It is imbalanced, in that it stresses improving overall quality more than enforcing minimum requirements that protect patients from harm. It is fragmented, in that Networks and State agencies rarely coordinate their efforts. And it lacks sufficient accountability on the part of the Networks, the State agencies, and, most of all, the facilities.

As HCFA provides leadership to address these shortcomings, we suggest that it (1) steer external oversight of the quality of dialysis facilities so that it reflects a balance between collegial and regulatory modes of oversight, and (2) foster greater collaboration between the Networks and State survey agencies. Specifically, we offer the following recommendations.

RECOMMENDATION 1. HCFA should hold individual dialysis facilities more fully accountable for the quality of care they provide.

- ▶ Revise the Medicare Conditions for Coverage for dialysis facilities so that they serve as a more effective foundation for accountability.
- ▶ Use facility-specific standardized performance measures to encourage facilities to improve the quality of care and to help ensure facilities meet minimum standards. Regularly issue reports incorporating comparative performance data and make them available to the facilities, the Networks, the State agencies, and the public.
- ▶ Strengthen the complaint system for dialysis patients and staff. Work with Networks and State agencies to develop an integrated complaint system that incorporates the following elements: accessibility, objectivity, investigative capacity, timeliness, responsiveness to complainants, enforcement authority and follow-up, improvement orientation, and public accountability.
- ▶ Enhance the role of Medicare on-site certification surveys by determining an appropriate minimum cycle for conducting the surveys and conduct pilot tests to determine the potential of Network and State joint initial certification visits of dialysis facilities.
- ▶ Facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes. Work with the Networks to establish pilot projects.

RECOMMENDATION 2. HCFA should hold the Networks and State survey agencies more fully accountable for their performance in overseeing the quality of care provided by dialysis facilities.

- ▶ Issue policy guidance delineating the distinctive roles of the Networks and State survey agencies and providing direction on how they should collaborate.
- ▶ Foster greater accountability of the Networks by developing a performance-based system for evaluating them and by increasing public disclosure of information on them.
- ▶ Foster greater accountability of the State survey agencies by establishing better means for assessing State surveys and by increasing public disclosure of information on the extent, nature, and results of the surveys.

COMMENTS ON THE DRAFT REPORT

We received written comments on the draft report from the Health Care Financing Administration, the Forum of End Stage Renal Disease Networks (the Forum), the Association of Health Facility Survey Agencies (AHFSA), and the American Association of Kidney Patients (AAKP). Overall, the reports received wide support. In the body of the report we summarize the major comments and offer our responses. Based on the comments, we changed one recommendation and made several technical changes.

HCFA's Comments

HCFA largely agreed with our recommendations. In response, HCFA offered a detailed action plan that addresses each of our recommendations. The plan demonstrates HCFA's commitment to publicly releasing facility-specific performance data, revising the complaint process, increasing on-site surveys, holding Networks more accountable for performance of their facilities, and assessing the performance of State survey agencies. HCFA did take issue with our recommendation calling for Networks and State agencies to conduct joint surveys for initial certification visits.

HCFA's action plan is a positive step toward implementing our recommendations and we urge HCFA to give it a high priority. In response to HCFA's concern about joint surveys, we changed our prior recommendation from one requiring such surveys to one urging that they be conducted on a pilot basis.

External Organizations' Comments

The external organizations supported the majority of findings and recommendations but also raised some concerns. The Forum expressed concern that some of our recommendations, especially the public release of facility-specific performance data, threaten patient confidentiality and undermine the collegial nature of the Networks. AHFSA expressed concern about the lack of funding for State survey agencies and AAKP urged that funding for strengthening oversight not come at the cost of patient activities.

We recognize patient confidentiality is critical, but we believe that mechanisms can be devised to ensure patient confidentiality. We want to emphasize that the Networks should not only take a collegial approach with facilities, but also must be willing to take more regulatory actions when warranted or to inform others, such as the State, that can take such actions. Finally, we recognize the significance of the concerns about funding. We address AHFSA concerns about the funding for State agencies by calling for HCFA to determine an appropriate minimum cycle for conducting surveys and we underscore AAKP's point that funding for oversight activities should not jeopardize patient care.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
INTRODUCTION	7
PRIMER ON DIALYSIS TREATMENT	10
THE IMPORTANCE OF EXTERNAL QUALITY REVIEW	11
FINDINGS	
Use of performance data to encourage improvements	13
Performance data rarely used to hold facilities accountable	13
Unreliable means for identifying and resolving complaints	15
Limited role of Medicare surveys	17
Medical injuries are not systematically monitored	20
Lack of accountability of the Networks and State survey agencies	20
RECOMMENDATIONS	22
COMMENTS ON THE DRAFT REPORT	35
APPENDICES	
A: Methodology	38
B: Major sources of clinical performance data for ESRD	40
C: Comments on the draft report	42
D: Endnotes	61

INTRODUCTION

PURPOSE

To assess external mechanisms the Health Care Financing Administration relies upon to monitor the quality of care provided by dialysis facilities to Medicare beneficiaries with end-stage renal disease.

BACKGROUND

About 3,200 dialysis facilities provide ongoing, life-sustaining dialysis treatments to about 230,000 patients with end-stage renal disease, or permanent kidney failure. Many of these patients are suffering from other complicated diseases such as diabetes and hypertension, and nearly all of them are Medicare beneficiaries. To foster improved care and minimize risks to patients, dialysis facilities conduct their own internal monitoring efforts. External review provides an additional safeguard.

External Review Bodies

The Health Care Financing Administration (HCFA) has the primary responsibility of ensuring beneficiaries receive appropriate care in dialysis facilities. To carry out the bulk of the oversight activities for dialysis facilities, HCFA relies upon two entities, End-Stage Renal Disease (ESRD) Networks and State survey agencies.

ESRD Networks. The 18 regional Networks are HCFA's main contractors for monitoring dialysis facilities, as they are the only entities created for and entirely devoted to the ESRD program. Federal statute requires Networks to assure the "effective and efficient administration of the benefits" provided under the ESRD program.¹ Network staff, typically 7 to 10 people, work closely with their board membership made up of local renal professionals. HCFA requires the Networks to conduct at least one HCFA-approved quality improvement project a year, to collect HCFA forms from facilities, and to resolve patient complaints. Networks also assist and educate facilities on issues related to quality improvement.

State Survey Agencies. HCFA relies upon State survey agencies, typically within departments of public health, to conduct Federal certification surveys and investigate complaints, both in accordance with the Medicare Conditions for Coverage. The Conditions for Coverage dictate the obligations of facilities under the Medicare program and are used by State surveyors to certify facilities.² Some State agencies have additional functions under their own State licensure program.³

External Quality Review Framework

We have identified four key elements that can be applied to any external quality review system for health care facilities. This framework is meant to be used by purchasers, such as Medicare, to ensure that dialysis facilities provide quality care, and by consumers, such as ESRD beneficiaries, concerned about the quality of care they receive in their facility. Each element in the framework provides a different perspective on the quality of care. For a comprehensive and effective external quality review system, all components need to be adequately addressed. Throughout our inquiry we relied on this framework to assess the overall effectiveness of the external review system for dialysis facilities.

Table 1. External Quality Review Framework for Dialysis Facilities	
Element	Description
Use of standardized performance measures	Standardized performance measures allow purchasers, consumers, and overseers to compare the performance of facilities or physicians. The comparison can examine a single facility over time or one facility against another. Such measures can be used for quality improvement activities and to enforce minimum standards.
Response to complaints	Complaints can come from patients, staff, and other interested parties. They can be of a particular instance of care or about broader matters concerning a facility's performance. The response to complaints can range from an off-site follow-up to an on-site investigation. The process can trigger corrective actions and system improvements.
On-site surveys	On-site surveys can be either announced or unannounced. Surveyors observe the conditions of the facility and equipment and interview patients and staff. The process can trigger corrective actions and system improvements.
Response to medical injuries	Medical injuries are adverse events attributable to medical management and unrelated to the patient's illness or underlying condition. The response to such events can range from minimal to thorough and can trigger corrective actions and system improvements.

Medicare Coverage of ESRD

In 1972, Medicare began providing coverage to individuals with ESRD making it the only entitlement criteria for Medicare based solely on a disease category.⁴ Medicare covers all treatment methods for patients: hemodialysis, peritoneal dialysis, and renal transplants. Patients receiving hemodialysis, the most common method, typically receive treatment in outpatient facilities three times a week. Peritoneal patients typically perform daily treatments at home and rely on outpatient facilities for ongoing support. (See Primer on Dialysis.) Medicare covers dialysis services performed by hospital-based and free-standing facilities. Hospital-based facilities are financially and organizationally integrated with a hospital whereas free-standing facilities are not.⁵

Our Inquiry

Our report focuses on the two main entities the Federal Government relies upon to oversee dialysis facilities: the State survey agencies and the Networks. We did not evaluate the activities of any one Network or State, rather, we assessed if the activities of the Networks and States overall create an effective external review system for dialysis facilities. Also, we did not evaluate the adequacy of the Medicare on-site survey process. This report is one of two from our overall inquiry. Our companion report, *External Quality Review of Dialysis Facilities: Two Promising Approaches*, presents two innovative initiatives used to monitor facilities.

We surveyed all 18 Networks, reviewed their annual reports for 1997 and 1998, and reviewed their responses to complainants for 1998. With eight Networks we held telephone interviews and reviewed their complaint logs for 1998. We also visited an additional five Networks. Over the course of these visits we spoke with patients, Network staff, and renal professionals (e.g., administrators, nephrologists, social workers, dietitians, nurses, and technicians.) We also analyzed data on the frequency of Medicare surveys, interviewed staff at 5 State survey agencies, and observed a survey in a dialysis facility.

Throughout our inquiry we interviewed HCFA personnel, including the project officers for the Networks. We also spoke with several renal professional organizations and patient advocacy groups. Finally, we conducted a review of scientific literature and Federal documents. (See appendix A.)

In the next section, we provide a brief overview underscoring why external quality review is so important as a patient protection mechanism. Then we present our findings and recommendations.

We conducted this study in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

PRIMER ON DIALYSIS

TYPES OF TREATMENT

Dialysis is the process of removing toxins from the body by diffusion across a semipermeable membrane, thereby compensating for kidney failure. There are two types of dialysis:

Hemodialysis. Removal of toxins directly from the patient's blood stream, requiring direct access to the bloodstream. The patient's blood is cycled through an artificial kidney, an external machine, that removes the toxins and excess fluids from the blood. The artificial kidney machine uses a semipermeable membrane, called a hemodialyzer, to filter out the toxins from the blood.

Peritoneal dialysis. Utilizes the patient's natural peritoneal membrane, located in the abdominal cavity, to remove toxins and excess fluids.

COMMONLY USED PERFORMANCE MEASURES

Adequacy. Refers to the amount of toxins, such as urea and creatinine, removed from the body during dialysis.

- ▶ **Urea reduction ratio (URR) and Kt/V.** Two measures used to measure adequacy in hemodialysis patients based on the removal of urea. The URR is a function of the amount of urea removed during dialysis, as determined by the pre- and post-dialysis blood urea nitrogen levels. The Kt/V is a function of the amount of urea removed multiplied by the time on dialysis, divided by the volume of urea distribution, or approximately the amount of water in the body. The National Kidney Foundation's Dialysis Outcomes Quality Initiative (DOQI) practice guidelines recommend a Kt/V of at least 1.2, or an average URR of at least 65 percent for the minimum delivered dose of hemodialysis.
- ▶ **Creatinine clearance and Kt/V_{urea}.** Two measures used to measure adequacy in peritoneal patients. Creatine clearance measures the removal of creatine and Kt/V_{urea} measures the removal of urea. DOQI recommends a weekly dose of continuous ambulatory peritoneal dialysis of at least 2.0 per week and a creatine clearance of at least 60L/week/1.73 m².

Anemia management. Anemia, or inadequate red blood cells, is a common concern among dialysis patients.

- ▶ **Hematocrit and hemoglobin.** Two measures of the severity of anemia. Hematocrit measures the ratio of red blood cells to the plasma volume, and hemoglobin measures the amount of a specific protein in red blood cells that carries oxygen. DOQI recommends a target range of 33 percent to 36 percent for hematocrit and between 11 g/dL to 12 g/dL for hemoglobin.
- ▶ **Ferritin level and transferrin saturation (TSAT).** Two measures used to monitor the level of iron. Ferritin is a measure of the level of iron stored within the body and TSAT is a measure of iron immediately available to produce red blood cells. DOQI recommends a ferritin level of 100 ng/mL and a TSAT 20 percent.

Vascular access. The point of direct access to the blood stream for hemodialysis. There are three types:

- ▶ **Catheter.** A tube is placed in a blood vessel, primarily used for temporary access to the blood stream.
- ▶ **Native arteriovenous fistula.** A patient's own artery and vein are joined surgically to allow arterial blood to flow through a vein, usually placed in the forearm and takes several weeks to mature. DOQI guidelines recommend that primary fistulas be placed in at least 50 percent of new patients.
- ▶ **Synthetic arteriovenous graft.** A synthetic blood vessel is used to surgically join the patient's artery and vein, usually placed in the forearm and takes several weeks to mature.

Nutrition. Inadequate nutrition is a common concern among dialysis patients.

- ▶ **Serum albumin level.** A measure of the level of proteins in the blood.

THE IMPORTANCE OF EXTERNAL REVIEW

Many dialysis facilities and corporations conduct their own internal quality monitoring and improvement projects. However, in order to protect patient safety, it is essential that an external oversight system exists to provide objectivity and public accountability that internal quality reviews lack. Below we present four key factors that underscore the need for external oversight in dialysis facilities.

Instances of Poor Care

Although dialysis treatment and patient outcomes have improved since the ESRD program began, much can and has gone wrong in facilities. Several well-publicized events in the media and in letters from patient advocates have documented cases of patient harm and have questioned the systems in place to protect patients.⁶ In the course of our review of documents we came across several examples where patients were put at risk due to inappropriate treatment. In our review of documents from the States and Networks we learned of cases where a patient received another patient's hemodialyzer, putting him at risk for blood-borne diseases; a patient in cardiac arrest was put at risk as facility staff searched for a misplaced code cart; a patient was exposed to a toxic disinfectant through his bloodstream when hooked up to a reused hemodialyzer that had not been rinsed properly;⁷ a patient received a drug overdose that resulted in prolonged bleeding and subsequent hospitalization; several patients received blood transfusions when a facility ran out of the appropriate medicine to treat anemia; and a patient's infected catheter was not removed in time, causing the patient to die of infection.

Vulnerable Patient Population

Dialysis patients are a vulnerable patient population that is growing. Many dialysis patients are elderly and suffering from other complicated illnesses such as diabetes and hypertension. Overall, the ESRD population is growing at a rate of 7 percent a year and for some of the more vulnerable types of patients, the growth rate is even higher.⁸ More importantly, dialysis patients depend on regular dialysis treatments for survival. In the words of one physician, dialysis is "intermittent, ambulatory life support."

Variation in the Quality of Care

HCFA's data indicate that a significant portion of dialysis patients fail to meet clinical practice guidelines developed by the National Kidney Foundation Dialysis Outcomes Quality Initiative. For the last quarter of 1998, 20 percent of a national sample of hemodialysis patients did not meet the guidelines' recommendation for the minimum dose of dialysis as measured by the Kt/V ratio.⁹ For the same period, 41 percent of hemodialysis patients failed to achieve a hemoglobin level that met or exceeded the target range recommended by the guidelines.¹⁰

Scientific literature also suggests variation in the quality of care dialysis patients receive. Several studies have shown that mortality rates vary significantly among facilities, even after adjusting for patient characteristics such as age and diabetes.¹¹ Other studies have shown variation at the patient and facility level in the delivered dose of dialysis.¹² One recent study found that higher mortality rates at facilities were associated with lower delivered doses of dialysis, after adjusting for patient characteristics.¹³ This same study also found that free-standing facilities, as opposed to hospital-based facilities, and lower amounts of physician supervision were associated with increased mortality rates. Another study found that patients treated in for-profit versus non-profit facilities had a 20 percent higher mortality rate and 26 percent lower rate of enrollment on a waiting list for a kidney transplant.¹⁴ The investigators of this study concluded, “Greater oversight or competing incentives to improve quality may be necessary to ensure that cost containment is not so extensive that it affects patient outcomes adversely.”¹⁵

Marketplace Pressures

The dialysis industry has grown significantly in recent years. The number of dialysis patients grew from about 160,000 in 1992 to 230,000 in 1997, the number of dialysis facilities increased from about 2,000 to over 3,000 — averaging about 200 new facilities each year.¹⁶ Most of this increase in facilities occurred among free-standing as opposed to the more traditional hospital-based facilities that receive an additional layer of oversight as part of the hospital. About 78 percent of dialysis patients receive treatment in free-standing facilities.¹⁷ Moreover, through a series of mergers and acquisitions, there has been increased consolidation in the ownership of the facilities. About 54 percent of dialysis patients receive treatment in facilities owned by one of three multi-national for-profit corporations.¹⁸

Along with growth and consolidation, the dialysis treatment environment is characterized by at least three other increasingly prominent forces: (1) increased competition for patients, (2) heightened concerns to contain costs,¹⁹ and (3) increased difficulty in finding and retaining experienced nurses and technicians in an increasingly competitive marketplace. Individually and cumulatively, these forces have caused service disruptions that can and have jeopardized patient care.

FINDINGS

The major strength of the external oversight system is the use of standardized performance measures to encourage improvements in the quality of care.

HCFA's performance data show improvements.

HCFA's Clinical Performance Measures Project collects a set of performance measures annually on a national sample of dialysis patients.²⁰ HCFA disseminates data to facilities that show national trends and Network variation. These data can serve as a stimulus for facilities to examine their own performance and to assess how it can be improved. The data show consistent improvements nationwide in patient outcomes since the project began in 1994. The percentage of patients achieving a mean urea reduction ratio 65 percent has increased from 43 percent in 1993 to 74 percent in 1998. Similarly, the percentage of patients achieving a mean hematocrit >30 percent has increased from 46 percent in 1993 to 83 percent in 1998.²¹ Even though these data are not facility-specific, Networks have drawn on these performance data to assess the overall performance of facilities in their region and to identify topics for regional quality improvement activities.

Networks' performance data also show improvements.

Networks through quality improvement projects and ongoing initiatives, collect performance data from facilities to help stimulate improvements. For example, one Network quality improvement project resulted in a 20 percent increase in the number of patients receiving the hepatitis B vaccine.²² Another Network project helped decrease the percentage of patients with inadequate peritoneal dialysis from 31 percent to 20 percent.²³ Several Networks have shown similar improvements by collecting and disseminating regularly a set of facility-specific measures; one Network even disseminates physician-specific reports.²⁴

Yet, the current system of oversight falls short in several respects.

Standardized performance data are rarely used to hold individual facilities accountable.

No requirement to collect a core set of facility-specific performance measures. Several entities, including HCFA, collect facility-specific performance data. (See appendix B.) However, these measures are housed across several databases, collected using different methodologies, and designed for different purposes. Networks have some access to these measures. States have almost no access. HCFA has not

established a facility-specific core data set that all facilities must report to one central location directly under HCFA's control. The closest that HCFA has come is the Clinical Performance Measures Project, but it is not facility-specific. On their own a few Networks collect facility-specific data, but this effort is limited to the facilities in their region.

The two main barriers reported by Networks to collecting facility-specific data are limited resources and no HCFA requirement. Networks are funded through statute. Statute requires that 50 cents of the composite rate facilities receive for each treatment goes towards the Networks.²⁵ Networks are not appropriated funds. Many Networks may not have the resources to collect and analyze additional data. Also, without a HCFA requirement, Networks do not think facilities will submit facility-specific data regularly.

Difficulty identifying poor performers. Without a national facility-specific core data set, most Networks and States are left with limited means of assessing the performance of individual facilities within their regions. In the few instances where Networks collect their own set of facility-specific data, they are left without comparable national data. Facility-specific data are necessary to identify facilities that are well below the regional mean or the accepted standard of care. Few Networks take full advantage of existing facility-specific data that they have access to and few Networks have a formal process for identifying outliers. HCFA does not require Networks to establish quantitative criteria to identify poor performers using existing facility-specific data. Networks complain that existing facility-specific data are limited, because they are too old, inaccurate, and not designed for performance assessment.

Limited Network authority to correct poor performers. Networks lack the authority to impose sanctions directly on facilities. In the cases where facilities are not cooperative or fail to make improvements, Networks must rely on either HCFA or the State survey agencies to take enforcement actions. Networks either can recommend to HCFA that it sanction a facility, or Networks can recommend to a State survey agency that it conduct a review of a facility. However, we found that some Networks are reluctant to make recommendations to HCFA or the State survey agencies for several reasons.²⁶ First, problems identified by the Networks may not fall directly under the Conditions for Coverage that HCFA and the States must rely upon when sanctioning a facility. Second, HCFA and the States are limited in the types of enforcement actions they can take.²⁷ Finally, Networks reported cases where HCFA and the States did not adequately follow-up with the Networks recommendations, leaving some Networks to conclude that referrals are futile.²⁸

Instead Networks typically seek to work with the facility collegially to correct the problem. Such efforts are likely to involve a meeting with key staff to discuss the facility's performance data and brainstorm about potential causes and solutions. In some cases, the Network will ask a facility to prepare a corrective action plan and will then

monitor adherence to that plan. Networks reported that, in most instances, this approach is successful.

Little sharing of data between Networks and State survey agencies. The Networks, as we noted, tend to have little facility-specific data to share. But even in cases where they have such data, they are not inclined to share it with the State agencies. In response to our survey of Networks, only 3 of the 18 reported that they routinely share facility-specific data with the States.

We identified two major barriers to Networks sharing data with the States. First, Networks fall under confidentiality laws that exempt them from Federal disclosure laws.²⁹ As such, Networks are reluctant to share data with the States because of concerns about eventual public disclosure. Second, Networks are concerned about the States using the data to take punitive actions. Networks officials fear that if the data are used in this way they will undermine their quality improvement efforts and their trusting relationships with facilities.

With respect to State agencies, information they collect as a result of their surveys of dialysis facilities could be useful to the Networks. But, even though much of this is public information, it does not tend to be shared with the Networks on a regular or timely basis.

Minimal public disclosure. Currently, neither HCFA nor the Networks make any facility-specific performance measures readily available to the public. HCFA does disclose facility-specific cost reports on its website, but this information requires some manipulation before it can provide useful performance data.³⁰ Networks, as we have previously mentioned, are exempt from public disclosure by statute. HCFA and others do disclose to the public data aggregated at the Network and national level, and in some cases, at the State level. Networks are especially reluctant to release facility-specific data to the public for fear of misinterpretation and of undermining internal quality improvement efforts. Most States will disclose survey results upon request.

The complaint systems serve as unreliable means for identifying and resolving quality-of-care concerns.

Throughout this report we use the term complaints generically to include concerns brought forth by patients, staff, or other individuals.

Barriers to lodging complaints. Two basic barriers inhibit patient complaints about the quality of care. First, dialysis patients find it difficult to complain about an individual or facility providing treatment that their lives depend upon. Network officials, other renal professionals, and patient representatives stressed that fear of retribution deters patients from complaining. The second major barrier is limited patient information and understanding about the technical aspects of their care. For example, a previous Office of Inspector General study found that although 73 percent of all patients reported

knowing there was a recommended level of adequate dialysis, only 36 percent could correctly identify the urea reduction ratio or the Kt/V as the test used to measure adequacy.³¹

In many respects, the staff in dialysis facilities are in the best position to lodge complaints about continuing problems with the quality of care in a facility. But as we were often reminded, staff also face significant deterrents to lodging complaints; such actions could put their jobs at risk and brand them as trouble-makers, thereby jeopardizing future employment in the field.

Network officials are aware of and often sympathetic to these barriers. But, in general, their policies and practices make the barriers even more imposing. First, they tend to discourage confidential complaints by stopping investigations short if complainants are unwilling to allow their name to be disclosed to the facility in question. Networks reported that it is difficult for them to investigate complaints fully without disclosing the complainants name to the facility. (Neither Networks nor States will release a complainant's name without consent.) Second, about half of the Networks require grievances to be in writing, before they take any action, unless it involves a life-threatening situation even though HCFA policy states that it is not necessary.³² Finally, Networks, and even more so the States, conduct little outreach to inform, let alone encourage, patients or staff to use the complaint system. The information that the Networks provide tends to be limited to posters sent to facilities and information packets sent to new patients. We found little evidence that Networks or States convey to patients that the complaint system is an important safeguard.

Limited investigations. HCFA looks to the State survey agencies to investigate complaints that involve life-threatening situations or possible violations of the Medicare Conditions for Coverage. The States conduct investigations on site that focus on the specific Medicare Conditions for which compliance is in question. If State surveyors believe it is warranted, they can extend the complaint investigation into a complete Medicare certification survey. Although HCFA has established complaints investigations as a top priority for States, the number of complaint investigations States conduct each year is minimal.³³ In 1997 and 1998, when about 230,000 dialysis patients received treatment under the auspices of about 3,200 dialysis facilities, we found that the States conducted only about 260 complaint investigations each year.

HCFA looks to the Networks to play a broader and a more front-line role in responding to complaints. Networks receive complaints covering a wide range of issues related to patient care and sometimes refer complaints to the States involving life-threatening situations or possible violations of the Medicare Conditions.³⁴ States also receive complaints directly.

Little national information is available on how many and what kind of complaints the Networks handle.³⁵ In an effort to gain some understanding of Network complaints, we conducted our own analysis of nine Network complaint logs for 1998. We found that

these nine Networks combined received over 700 complaints. However, the majority of these complaints did not involve quality-of-care concerns. About 45 percent were actually requests for information and 13 percent involved concerns expressed (typically by staff) about disruptive patients. Of all the complaints, 25 percent concerned service quality (e.g. temperature of facility, waiting times, friendliness of the staff) and 15 percent technical quality (e.g., clinical care, adequacy of equipment).³⁶

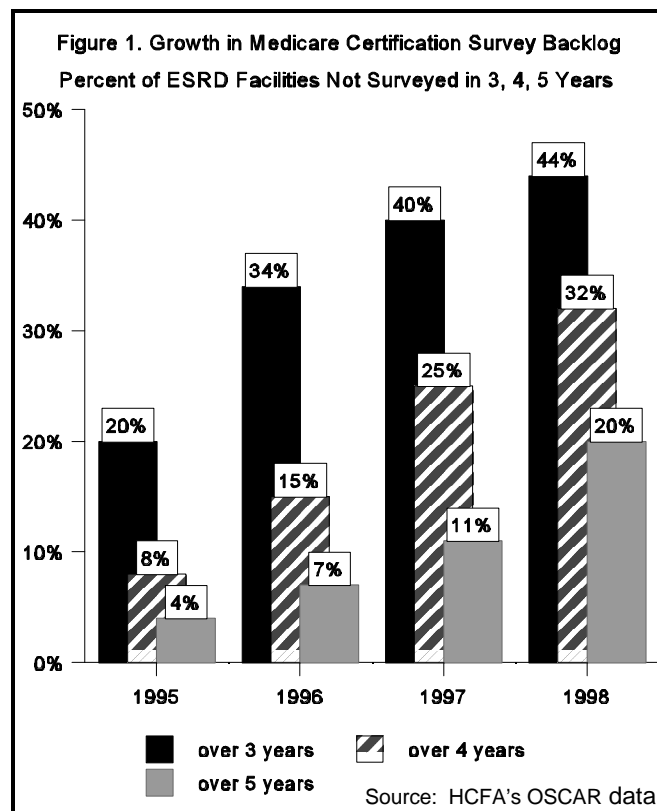
In response to our survey, the 18 Networks reported that they investigated 170 complaints in 1998, only 34 of which involved a site visit. Most Networks encompass many States and have limited resources for in-depth complaint investigations. Network investigations, in accord with HCFA instructions, typically facilitate quick resolution between the complainants and the facilities. Networks address most problems by working collegially with facilities. We also found that Networks rarely conduct (or have the resources to conduct) pattern analyses to identify trends in complaints with the intent of identifying and correcting systematic problems.

Fragmented process for responding to complaints. Working single-handedly, neither the States nor the Networks can tap the full potential of a complaint system that effectively addresses quality-of-care concerns. Through their board membership, Networks have important clinical expertise in nephrology that gives them substantial ability to assess and follow up complaints regarding the adequacy of the clinical care being provided. But the Networks have little authority to enforce corrective actions. The States, on the other hand, have enforcement authority for violations of the Medicare Conditions for Coverage, but tend to lack the clinical expertise concerning renal care. Little coordination occurs between States and Network. The Networks do refer to the State agencies complaints which concern the Medicare Conditions. We found that in 1998 each Network referred, on average, three complaints to the States. But, the Networks report that the State agencies do not routinely inform them of the results of complaint investigations or even whether they conducted an investigation. Similarly, Networks themselves do not tend to be any more forthcoming in informing the States of their own investigations. In the same vein, Networks and State agencies seldom undertake combined investigations in response to complaints about the quality of care.³⁷

Medicare certification surveys play a limited role in ensuring facilities meet minimum standards.

HCFA relies solely upon the State survey agencies to conduct on-site certification surveys to ensure a facility's compliance with the Medicare Conditions for Coverage.³⁸ States conduct an initial survey of all newly established facilities to ensure that they meet minimum standards. Thereafter, States conduct recertification surveys to ensure ongoing compliance. Both surveys, particularly the recertification surveys, provide an opportunity to examine the actual day-to-day practices of the facility. Some of the major components of a dialysis facility survey include: examining the reuse of hemodialyzers and water treatment areas, interviewing patients and staff, observing personnel, and reviewing patient medical records and personnel files.

The elapsed time between Medicare surveys is increasing. In 1995, 20 percent of ESRD facilities had not been surveyed in the past three years.³⁹ By the end of 1998, that number had grown substantially to 44 percent of facilities not receiving a survey in the past three years. (See figure 2.) Ten percent of facilities had not been surveyed in 6 years or more by the end of 1998. The average elapsed time between surveys had doubled between 1994 and 1998, from once every 1.7 years in to once every 3.4 years⁴⁰ In fact, during 1998, States surveyed only 17 percent of facilities. This is a dramatic decrease compared to 1993 when over 50 percent of facilities received a survey.⁴¹



A major reason for the decline in ESRD surveys is competing budget demands.⁴² Nursing homes and home health agencies both have mandatory survey cycles established by Congress.⁴³ As a result, nursing homes and home health agencies receive funding priority over ESRD facilities, which lack such a mandate. In addition, ESRD facilities are included under the category of non-long term care providers, which also includes non-accredited hospitals, psychiatric hospitals, ambulatory surgical centers, and hospices. All of these providers compete for the same pool of resources allocated by HCFA. Currently, non-long term care facilities appear tenth on a list of 12 HCFA workload priorities for State agencies.⁴⁴

Medicare Conditions for Coverage for dialysis facilities provide an inadequate foundation for accountability. Established in 1976, the Conditions fail to reflect major changes in the delivery of dialysis services, in the organizational auspices of dialysis facilities, and in the concepts of quality oversight and quality improvement. During our inquiry, the following emerged as particularly notable shortcomings:

- ▶ ***The facility governing body is insufficiently accountable for the quality of care facilities provide.*** The Conditions do not explicitly hold the governing body accountable for overall patient care and outcomes.⁴⁵ In practice, responsibility is often diffused among administrators and distant parent corporations. At times, this makes it difficult for the Networks and State survey agencies to get timely information and sustained attention to corrective actions.

- ▶ ***The medical director has limited authority and as such is inadequately accountable for the quality of care.*** Medical directors and Network officials often stressed to us that medical directors tend to exert little influence over the day-to-day care offered in dialysis facilities and have little authority to do so. They are particularly frustrated when attending nephrologists do not engage in quality improvement efforts or address situations where medical directors thought patients were receiving inadequate care. These are serious limitations addressed only indirectly in the existing Medicare Conditions.⁴⁶
- ▶ ***Facilities are not required to report electronically on standardized performance measures determined by HCFA.*** The limited capacity of some facilities to provide electronic submission of data has inhibited Network initiatives to collect facility-specific data. Under HCFA's plans for collecting and using clinical performance data in the years ahead, it will be essential for facilities to meet standard specifications for electronic reporting.
- ▶ ***Facilities are not required to conduct their own quality improvement program.*** The Medicare Conditions only require facilities to monitor specific events and do not explicitly require facilities to continually improve care and/or to identify trends in care. Without such a mandate, and in facility settings where the pressures of providing adequate day-to-day care are considerable, it is often difficult to devote much attention to deliberative efforts that would identify improvement needs, to collect and analyze data concerning those needs, and then to determine and monitor changes in facility practices.
- ▶ ***Facilities are not required to monitor patient satisfaction.*** Patient satisfaction is an important, often overlooked dimension of quality. The Medicare Conditions do not require facilities to routinely monitor patient satisfaction. Some Networks have taken the initiative to develop and encourage the use of patient satisfaction surveys. Similarly some dialysis facilities and corporations have developed patient satisfaction surveys.

State survey agencies have difficulty maintaining the expertise of surveyors.

Facility, Network, and State agency staff view the Medicare surveys as an important part of external oversight. However, they raise concerns about the skills of the surveyors. They stressed that dialysis surveys are highly technical, requiring knowledge not only of water treatment processes but also of the complexities of dialysis treatment. As dialysis surveys become less frequent, surveyors are increasingly hard pressed to maintain their familiarity with dialysis facilities, let alone keep pace with technological advances.

HCFA does require all surveyors to attend a basic training course specific to dialysis facilities before they can conduct dialysis surveys.⁴⁷ HCFA also provides advanced training courses regularly.⁴⁸ However, lessons learned in these courses may be forgotten if surveyors do not have the opportunity to use these skills regularly.

Medical injuries are not systematically monitored.

Medical injuries are attributable to the care provided to the patient, not to the patient's underlying conditions. Such injuries can happen even in the best of health care facilities.⁴⁹ Some dialysis corporations may have internal systems for addressing medical injuries, but, if they do, little is known about their scope and effectiveness. Some States have adverse event reporting requirements, but they appear to be of little overall consequence to dialysis facilities.⁵⁰ Facilities that are associated with hospitals accredited by the Joint Commission for Accreditation of Healthcare Organizations are subject to the Commission's "Sentinel Event" program for reporting adverse events, but as we have shown in a prior report, this system is still in an early stage of development.⁵¹ HCFA lacks any requirement that facilities establish their own, internal systems for identifying and analyzing adverse events or that they report such events to Networks or States.⁵²

HCFA Does Little to Hold Networks and State Survey Agencies Accountable for Their Effectiveness.

Minimal assessment of Networks' performance.

Project officers in four regional offices are HCFA's main operational contacts with the Networks. These project officers receive considerable information from the Networks. They get regular updates on the quality improvement projects that Networks are mandated to conduct. They conduct periodic site visits, receive quarterly reports providing detailed updates on the Networks' activities, and receive annual reports with a comprehensive summary of the year's activities.

However, this regular flow of information results in little substantive evaluation and feedback on the effectiveness of the Networks. How effective are the Networks in using standardized performance data to foster overall improvement across facilities and, in particular, in poorly performing facilities? How successful are they in operating a complaint system that is accessible, fair, and responsive to complainants? We found few signs of probing, independent assessments of these and other such basic questions. Nor does HCFA call for the Networks themselves to address such evaluative questions in more than a passing way.

HCFA's most formal mechanism for evaluating the Networks is the year-end evaluation questionnaire that the project officers complete and send to the central office. This is a three-page form that poses 13 performance-related questions, and in each case, calls for the project officer to indicate "satisfactory," "unsatisfactory," or "comments attached."⁵³ In our review of the completed questionnaires for all 18 Networks in 1998, we found that in the total inventory of 234 questions, all but 2 were checked satisfactory.⁵⁴

Further HCFA does not hold the Networks accountable for how the facilities in their regions fare on HCFA's Clinical Performance Measures Project. There are notable differences from Network to Network. For example, across all 18 Network regions, the percentage of hemodialysis patients with a Kt/V 1.2 ranged from 74 percent to 87 percent for the last quarter of 1998. Similarly, the percentage of hemodialysis patients with hemoglobin levels >10 gm/dL ranged from 72 to 85 percent among the Networks.⁵⁵ In this context, it is important to note that HCFA gives the Networks little discretion to undertake a range of quality improvement activities targeted to the distinctive needs of their region. Instead, HCFA requires them to conduct formal quality improvement projects that can take years to complete and that must follow a prescribed format.

Minimal assessment of State survey agencies' performance.

HCFA's assessment of the performance of the State survey agencies is even less exacting than that for the Networks. In the past, HCFA would conduct validation surveys, through which HCFA staff would review dialysis facilities shortly after a State certification survey.⁵⁶ Recently, HCFA eliminated these in favor of periodically observing State surveyors' performance and offering advice and assistance as applicable. While the latter approach has potential and may well involve some useful informal assessment and feedback to the State surveyors, we found no evidence of substantive evaluation and feedback to the States on such key matters as the effectiveness of the surveys, the skill of the surveyors, and the adequacy of collaboration with the Networks.

HCFA relies on State agencies to assess their own performance and, by working with the HCFA regional offices, to develop and implement their own quality improvement plans. This process is called the State Agency Quality Improvement Program (SAQIP). The program addresses State survey activities generally, and fails to specifically assess dialysis surveys. The summary report that HCFA issues on SAQIP activities provides few meaningful insights into the challenges or successes of any one State.⁵⁷

Minimal public disclosure.

HCFA offers no readily accessible public information (e.g., on the Internet) on any Network or State actions taken by either Networks or States to protect the public. All Networks have websites, but they vary significantly in the amount and type of information that they post. None publishes any information on complaints received and investigated at a particular facility or on any corrective actions pending against a particular facility. Similarly, little information is readily available on the performance of States. Survey results are available only upon request and are difficult to interpret. Results are not routinely posted on the Internet or in facilities.

RECOMMENDATIONS

The 230,000 patients receiving life-sustaining dialysis treatments rely upon the professionalism of their caregivers and the internal monitoring efforts of their facilities to provide high quality care and minimize risks. Yet, documented variations in the quality of dialysis care and reported incidents of poor care reinforce the need for an external quality review system to serve as a safety valve for patients.

As we have indicated, the quality oversight system carried out on HCFA's behalf by the Networks and State agencies has major shortcomings. It is imbalanced, in that it stresses improving overall quality more than enforcing minimum requirements that protect patients from harm. It is fragmented, in that Networks and State agencies rarely coordinate their efforts to foster patient protections. And, fundamentally, it lacks sufficient accountability on the part of the Networks, the State agencies, and, most of all, the facilities themselves.

HCFA should exert leadership to address these shortcomings. In this section, we present two guiding principles and two recommendations that address how HCFA can provide this leadership. In doing so, we stress that while HCFA has authority and leverage, it must approach the Networks and State agencies as partners who contribute to and share a commitment to high-quality dialysis care. We also stress that external oversight must be conducted in ways that minimize the regulatory burden on dialysis facilities and seek to complement the facilities' own internal quality review efforts. In some cases HCFA has already undertaken initiatives that move in the directions we call for.

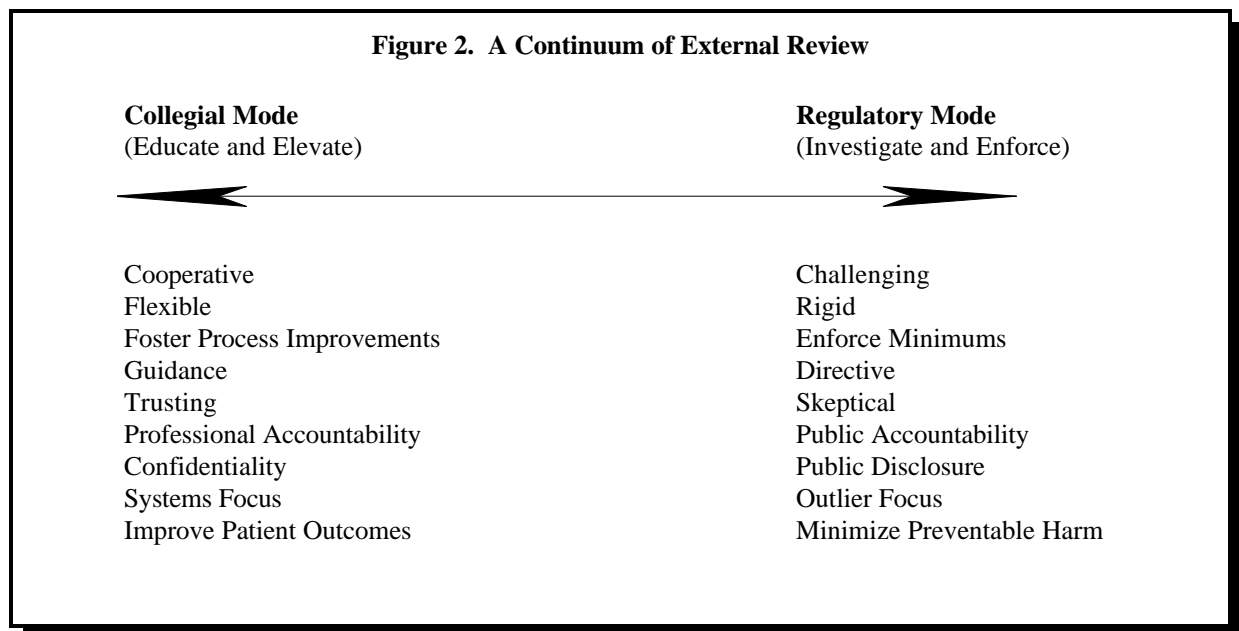
We present our recommendations in the context of the current oversight system in which HCFA relies upon the Networks and State survey agencies. We believe that this system has the potential to provide effective oversight. Yet, we recognize and suggest that HCFA take into account that a system for private accreditation of dialysis facilities, if held properly accountable, can be a valuable complement — particularly because it can readily adapt state-of-the art standards that respond to changes in dialysis delivery and evaluation methodology.⁵⁸

In making our recommendations, we must stress that our focus is on the external quality oversight of dialysis facilities and not on the Medicare payment policies concerning dialysis treatment. We note that because in the course of our interviews and in the professional literature many parties have expressed concern that the fragmented nature of the payment system and the current rate of reimbursement for dialysis treatment are themselves factors that may adversely effect the quality of dialysis care. We offer no such evidence in this report, but recognize that they are factors warranting attention, as has been pointed out by the Institute of Medicine and the Medicare Payment Advisory Commission.⁵⁹

Finally, we recognize that our findings and recommendations suggest a sense of urgency in improving the quality oversight of dialysis facilities. At the same time, we recognize that in an environment of limited resources and competing priorities, all the actions we call for cannot readily be taken. We present them as a blueprint for actions that can be carried out over a reasonable period of time.

GUIDING PRINCIPLE 1. HCFA should steer external oversight of the quality of dialysis facilities so that it reflects a balance between collegial and regulatory modes of oversight.

In our work on external quality oversight of various kinds of health care providers, we have found it helpful to consider oversight efforts in terms of a continuum, characterized by a collegial approach on one side and a regulatory approach on the other. External reviewers in the collegial mode focus on educating and improving performance; those in a regulatory mode focus on investigating and enforcing of minimum requirements. In the continuum below, we present the major characteristics we associate with each mode.



Both approaches have value and ardent supporters. But, as the National Roundtable on Health Care Quality and others have found, neither approach is backed with sufficient data to warrant concentrating on one at the expense of the other.⁶⁰ A credible system of external review must, therefore, reflect a reasonable balance between the two.

In the current system of oversight, the State agencies clearly operate on the regulatory side of the continuum. They are public bodies that as HCFA's agents perform on-site surveys that can serve as the basis for regulatory actions. But as we have shown, the

frequency of those surveys has declined markedly, resulting in only 17 percent of all dialysis facilities being surveyed in 1998.

In contrast to the State agencies, the Networks function on the collegial side of the continuum. They are governed primarily by physicians who are associated with individual facilities, who have expertise on dialysis treatments that State agency representatives lack, and who stress education and improvement objectives. As we have shown, their collegial orientation, which can often be effective, is apparent in how they use standardized performance data and respond to complaints. Some Networks do reflect a greater readiness to take a more challenging approach to facilities, but their limited authorities, resources, and mandate from HCFA preclude them from moving very far in this direction. In working with the Networks, HCFA in recent years has reinforced their collegial role, viewing them increasingly as functioning in a penalty free environment, while the State agencies serve as the regulators.

The Networks have much to offer in using collegial approaches to foster improvements in the quality of care. Given their greater expertise on dialysis matters and their closer relationships with dialysis facilities, it would seem to be desirable for HCFA to look to them to tilt toward the collegial end of the continuum. But it is not feasible for a Federal oversight entity not to have some clear requirements for enforcing minimum standards of performance. HCFA, we believe, should exert a steering role that, over time, achieves a reasonable balance between the two approaches to oversight. In our recommendations, we offer specific suggestions on how that can be done.

GUIDING PRINCIPLE 2. HCFA should steer the external oversight of dialysis facilities so that Networks and State survey agencies collaborate more effectively.

As we have shown, the Networks and State agencies operate in two separate realms and rarely interact. Given the crucial and often interrelated roles that both play as HCFA's agents, it is vital that HCFA provide direction that facilitates better collaboration. Through a clear delineation of their mutual roles, specific operational mandates, support for demonstration efforts, sharing of information about promising approaches, and perhaps other ways, HCFA can steer the efforts of the Networks and State agencies in ways that foster more frequent and effective collaboration. The joint efforts taking place in Texas illustrate some of the potential that exists. (See our companion report, *External Quality Review of Dialysis Facilities: Two Promising Approaches*.)

RECOMMENDATION 1. HCFA should hold individual dialysis facilities more fully accountable for the quality of care.

1a. HCFA should revise the Medicare Conditions for Coverage for dialysis facilities so that they serve as a more effective foundation for accountability.

The current Conditions are close to a quarter century old.⁶¹ It is time for HCFA to update and reinforce them as a tool for holding dialysis facilities accountable for the quality of care they provide. A number of years ago, HCFA proposed a set of revisions that reflected some progress in this direction. But that effort stalled. We recommend that HCFA revise the current Conditions so that, at a minimum, they:

- ▶ ***Strengthen the accountability of the dialysis facility governing body.*** The governing body should be held clearly accountable for the overall quality outcomes provided by the facility.⁶² Moreover, since most dialysis facilities are now part of national or multi-national corporations, the governing bodies should ensure that authoritative representatives are readily available to respond to queries and/or visits by State survey agencies or Networks.⁶³
- ▶ ***Reinforce the accountability of the dialysis facility medical director for patient care.*** While the governing body of the facility is the basic source of accountability, the medical director should clearly be empowered as the on-site agent most directly responsible for the quality of care being delivered. In this capacity, the medical director should clearly have the authority to develop and monitor quality improvement efforts, to serve as an educational resource for medical and nursing staff, and, where individual care staff are not performing adequately, to bring that to the attention of the facility's designated governing authority.⁶⁴
- ▶ ***Require facilities to report electronically on standardized performance measures determined by HCFA.*** HCFA must make clear a facility's obligation to report facility-specific patient outcome data to a designated entity or entities on a national set of performance measures.⁶⁵ As HCFA continues to focus more on performance measures, facilities must submit their data electronically in order to make this task feasible and allow for timely analysis and dissemination of the data.
- ▶ ***Require dialysis facilities to conduct their own quality improvement program.*** An internal quality improvement program serves as a valuable complement to network-wide or national improvement efforts. It is a mechanism for addressing the distinctive needs of a facility and of fostering a culture of continuous improvement.⁶⁶

- ▶ ***Require dialysis facilities to establish internal systems for identifying and analyzing the causes of medical injuries and medical errors.*** Injuries associated with patient care will happen from time to time and a facility must be alert to spotting them and learning from them. Such internal systems help protect patients from harm.
- ▶ ***Require dialysis facilities to monitor patient satisfaction.*** Over the past 25 years, patients have come to play an increasingly important role in their own health care, and techniques of assessing patient satisfaction have become increasingly sophisticated. Given that, it is reasonable to expect dialysis facilities to integrate patient satisfaction as an element in their own quality improvement efforts. Moreover, an ongoing mechanism for monitoring patient satisfaction can serve as a way of surfacing patient concerns that complaint systems do not.⁶⁷

1b. HCFA should use facility-specific performance measures to encourage facilities to improve the quality of care and to help ensure facilities meet minimum standards.

We recommend that HCFA move in the direction of collecting and disseminating *facility-specific* performance data and of using such data in a balanced fashion — for both improvement and enforcement purposes. HCFA has made progress in developing and using performance measures that provide the basis for assessing the quality of dialysis care. But, thus far, HCFA has focused on using performance measures almost completely for improvement purposes by focusing on national and regional trends. It is time, we believe, to build on this progress by using performance measures as a key mechanism for holding individual facilities more accountable for the care they provide.

Identify a core set of performance indicators to collect regularly on all patients from facilities. HCFA, with input from the professional community and from patients and patient advocates, should determine a core set of clinical indicators that will be used to help facilities, Networks, State survey agencies, and the public assess the quality of care at a facility while ensuring patient confidentiality. Once established, this core data set should be continually examined and revised so that it includes the most pertinent, reliable measures. HCFA has already implemented core data sets for other providers, such as nursing homes and home health agencies, which serve vulnerable patient populations. It is time to do the same for dialysis facilities. In the interest of accuracy and timeliness, HCFA should develop a system that collects the performance data on a regular basis directly from patient's medical records. At a minimum HCFA should collect these measures annually and work towards quarterly reporting.

HCFA has already begun to take significant steps toward the goal of facility-specific data. Namely, HCFA has invested in an extensive computer infrastructure for electronically linking facilities, Networks, and HCFA together. This system will make a data collection of this size more feasible.⁶⁸ HCFA has also created the National ESRD Core Data Set Initiative to begin to develop a core data set for dialysis facilities.

Already, HCFA has funded the creation of three facility-specific reports. One facility-specific report is to be used by Networks and the facilities for quality improvement purposes.⁶⁹ HCFA has also developed two other facility-specific reports that will contain performance data, one for State survey agencies and one for consumers.⁷⁰ These three reports rely largely on HCFA billing data for clinical indicators such as urea reduction ratios, hematocrit levels, and patient mortality.

Disseminate comparative facility-specific reports to facilities, Networks, State survey agencies, and the public containing all the performance indicators in the core set. Once HCFA has a data collection system in place, it should generate quarterly, facility-specific reports that compare facilities to their own past performance and to their peers at the State, Network, and national levels for each of the performance indicators in the core set. Where possible, HCFA should account for case mix differences among facilities. At a minimum, this should include patient demographic information. Eventually, HCFA should generate similar reports at the physician level.

The data in these reports should be made readily available to all parties: the facilities, the Networks, the State agencies, and, through Internet websites (and perhaps even postings in facilities), the general public. Such an effort will require HCFA to ensure patient confidentiality and may call for statutory changes. As we previously mentioned, HCFA already has an effort underway to develop a core data set, the National ESRD Core Data Set Initiative. However, HCFA has not yet determined specifically how this data set will be used by all the various parties.

Figure 3. The core set of facility-specific performance measures should be available to:

- ▶ **facilities** to support internal quality improvement activities,
- ▶ **Networks** to support regional quality improvement activities and to identify outliers for further review,
- ▶ **State survey agencies** to help guide and inform the survey process, and
- ▶ **the public** to foster public accountability.

We also recognize the sensitivities associated with such widespread release of this information. The data, many note, can be misleading. For instance, some patients may not choose to have optimum dialysis treatments because they wish to spend less time on dialysis. To help foster the responsible use of the performance data, we suggest that all quarterly performance reports include a prominent statement up front noting the limitations of the data and emphasizing that performance data are *indicators*, not absolute markers of quality.

At the core, the performance data can help reviewers ask better, more targeted questions about quality. If a facility's performance on a measure or a cluster of measures has been declining over time or is consistently less than that of other facilities with a similar patient mix, then it is reasonable to ask why and to do so in a public forum. The answers

might well indicate that such a facility is actually a top-quality one, with sound reasons for its statistical ranking. Or, they could indicate that the facility does have problems warranting attention.

- ▶ **Facilities.** Perhaps the most compelling reason for distributing facility-specific standardized performance data is to spur internal improvements by the facilities themselves. Such data can help leadership in the facilities gain a better sense of how the facility is performing and can provide the leadership with valuable leverage for initiating change. This would appear particularly true in competitive markets.
- ▶ **Networks.** Once equipped with facility-specific performance data, Networks will have a valuable additional tool to guide their external oversight of facilities. HCFA should require that Networks use these data for both improvement and enforcement purposes. It should look to the Networks to take the lead in identifying best practices, conducting educational and technical assistance efforts, and other initiatives that foster continuous improvement in the quality of care provided at dialysis facilities. At the same time, HCFA should look to the Networks to work with outlier facilities that have continued poor performance that cannot be explained by extenuating circumstances. HCFA should also make clear that this may well call for imposing corrective actions, or perhaps, referrals to the State survey agencies or HCFA itself.
- ▶ **State survey agencies.** The professional renal community is concerned about the potential use of performance data to trigger State surveys. Their concern centers around the credibility of such information in identifying problem facilities and in the use of performance data for regulatory as opposed to improvement purposes. We recognize the danger of drawing upon performance data too literally as an alarm-call for a regulatory-focused State survey. Yet, we see no basis for not regularly sharing such data with the State surveyors. Together with other information that the State may have on a facility, it can help guide the surveyors when they do survey a facility or, in cases when the information seems compelling enough, influence when they decide to conduct a survey.⁷¹
- ▶ **The public.** With the rapid advances taking place in information and medical technology, patients and consumers, in general, are becoming increasingly active partners in their own health care.⁷² Even though many dialysis patients may not be inclined to draw on facility performance data, many of them and many family members, surely would be interested in such data. Moreover, the influence of public release would likely contribute to how seriously facilities respond to the data. HCFA has moved in this direction in providing data on the performance of nursing homes and managed care organizations.⁷³ It should do the same for dialysis facilities. HCFA's posture toward performance data should be that if they are worth collecting, they are worth disclosing.

1c. HCFA should strengthen the complaint system for dialysis patients and staff.

Work with the Networks and the State survey agencies to establish an effective complaint system. On the basis of this inquiry and our prior inquiries of external quality oversight of health care providers, we have developed a template for an effective complaint system. Below, we identify and explain the eight key elements of that template. We present it here as a frame of reference for the kind of system that HCFA should seek to establish in the dialysis field.

Table 2. Template for an Effective Complaint System	
Element	Description
Accessibility	Makes efforts to inform potential users of the system and is easy to use.
Objectivity	Respects the rights of all parties involved. Conducts unbiased investigations.
Investigative Capacity	Has access to clinical expertise and has sufficient resources and authority to thoroughly review and evaluate complaints, including the ability to go on-site whenever necessary.
Timeliness	Complaint investigations conclude within a reasonable time frame.
Responsiveness to Complainants	Complainants receive substantive information about the process and any resulting actions.
Enforcement Authority and Follow-up	Has the authority to hold facilities and individuals accountable when complaints are substantiated. Follows up with appropriate corrective actions.
Improvement Orientation	Uses complaints to help identify opportunities for improvement and prevention.
Public Accountability	Facility-specific complaint information is available to the public so that they can be aware of any disciplinary actions or any past problems at a particular facility.

Conduct pilot projects to test ways in which the Networks and the State survey agencies could work together to create an integrated complaint system. Given the fragmented nature of the current complaint systems, we recognize that even at best it is likely to take some time to develop a system that as a whole reflects the characteristics of the above template. Thus, we urge HCFA first to convene representatives from the Networks and State survey agencies to identify ways in which these two entities can work together most constructively, drawing on their respective strengths. Secondly, we urge HCFA to conduct pilot efforts through which Networks and State agencies implement a unified complaint system based on our template. The results of such pilots could help guide the efforts of other Networks and States and, over time, could provide the basis for explicit expectations incorporated in HCFA contracts with both the Networks and States.

Develop a common instrument that facilities and others could use to assess patient satisfaction. For many patients, an anonymous response to a patient satisfaction survey may serve as a safer vehicle for expressing concern than a formal complaint to a facility, Network, or State agency. We have already called for HCFA to revise the Medicare Conditions for Coverage so that facilities are required to conduct their own assessments of patient satisfaction. Given the importance of this kind of effort, we also call upon HCFA to exert national leadership to facilitate the development of a common instrument that dialysis facilities could use to assess patient satisfaction. This could draw upon the instruments that some dialysis corporations have already developed and use for their own internal monitoring efforts. HCFA could make such an instrument available to facilities for their own use. HCFA could also test such an instrument on a national, Network, or even facility-specific basis. Recently, the Medicare Payment Advisory Commission made a similar recommendation.⁷⁴

1d. HCFA should enhance the role of Medicare on-site certification surveys.

Determine an appropriate minimum cycle for conducting Medicare certification surveys of dialysis facilities. Routine on-site surveys of dialysis facilities are important to help ensure that facilities comply with minimum standards outlined in the Medicare Conditions for Coverage.⁷⁵ But, as we have shown, the elapsed time between the State surveys has been growing, with the result that close to half of all facilities have not been surveyed within a 3-year period. As a result, surveyors have difficulty maintaining their skills.⁷⁶ By contrast, nursing homes and home health agencies, which also serve vulnerable populations, are surveyed according to a congressionally mandated cycle. By determining an appropriate minimum cycle for dialysis facilities, HCFA will increase the attention that dialysis quality issues receive and will enable surveyors to better maintain their competencies.

Conduct pilot tests to determine the potential of Network and State joint initial certification visits of dialysis facilities. All new facilities must undergo an initial certification visit by the State survey agency. We suggest that this initial review presents a major opportunity for State agencies and Networks to bring together their respective strengths and ensure that the facilities have in place the necessary elements to provide top-quality dialysis care. We recognize that at the time of initial reviews few patients are receiving treatment at the facility and therefore major problems rarely are uncovered. We think that initial reviews provide an opportunity for the Networks and States to work together cooperatively without the pressures associated with a for-cause investigation. Such a joint effort would get the two entities more accustomed to working together and could therefore have residual benefits for their other oversight functions.

1e. HCFA should facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes.

We have already recommended that HCFA require facilities to develop their own, internal mechanisms for addressing medical injuries and medical errors. It is essential,

we believe, for this internal safeguard to be complemented with an external, publicly accountable means for addressing adverse events resulting in death or serious harm while ensuring patient confidentiality. The Institute of Medicine recently called for a mandatory national system for reporting of such adverse events in hospitals and other health care facilities.⁷⁷ Given that dialysis treatments are paid for primarily by Medicare funds, and that HCFA has the major responsibility for the external quality oversight of the facilities, dialysis facilities are an ideal candidate for testing this kind of reporting system. The system should provide for the analysis of adverse events and for any necessary corrective actions at the facilities involved. It should also involve the maintenance and regular analysis of a data base of such events in order to identify injury-prevention strategies that could be shared across facilities.

In particular, we suggest that HCFA work with the Networks to establish pilot efforts to conduct such monitoring. Those pilots should test ways to identify major adverse events occurring in dialysis facilities that trigger subsequent analyses that shed light on (1) the causes of the events in those facilities and (2) the broader prevention strategies that can be taken across facilities. In any such pilot effort, HCFA should require that collaborative arrangements be made with the State survey agencies.⁷⁸

RECOMMENDATION 2. HCFA should hold the Networks and State survey agencies more fully accountable for their performance in overseeing the quality of care provided by dialysis facilities.

The Networks are private, federally funded contractors accountable to HCFA for their performance. The State survey agencies are public bodies accountable to their States' governors and legislatures, but also to HCFA for the services they are providing on behalf of Medicare beneficiaries. If HCFA is to hold the facilities more accountable as we called for in the prior recommendations and if it is to continue to rely upon the Networks and State agencies as its main agents toward that end, then it must also find ways to hold those agents more accountable. Below, we set forth specific actions HCFA can take.

2a. HCFA should issue policy guidance delineating the distinctive roles of the Networks and State survey agencies in quality oversight and providing direction on how they should collaborate.

HCFA should clearly state that the Networks serve as its primary agents in fostering continuous quality improvement in the care provided to dialysis patients, but yet must also support enforcement efforts. Similarly, it would be helpful for HCFA to clearly state that the State survey agencies serve as HCFA's primary agents in enforcing compliance with the Medicare Conditions for Coverage, but also must support improvement opportunities. With the two entities having a mutual appreciation of these distinctions, the stage is more effectively set for effective joint efforts — for a more effective oversight process that marries the clinical expertise of the Networks with the

regulatory powers of the State agencies. HCFA can convey this in two ways. For Networks, their contracts, particularly in the section explaining HCFA's Health Care Quality Improvement Program, would seem to be a particularly appropriate vehicle. For the State agencies, the annual budget call letter would appear to be the most appropriate forum.

We recognize that there are significant barriers to achieving collaboration between the Networks and the States. As we have already mentioned, Networks and States take markedly different approaches to oversight. Also limited resources make it difficult for the States and the Networks to have face-to-face meetings. This may be even more difficult for the Networks because most Networks cover multi-state regions. Finally, HCFA needs to address the issue of confidentiality and if necessary request statutory changes so that the Networks and the States can disclose information to one another and to the public.

HCFA should also target, for both the Networks and State agencies, particular spheres of activity in which collaborative arrangements are not only desirable, but also necessary. HCFA should go beyond the general statements on coordination, as now appear in the Network contracts, and offer firm direction. HCFA should then hold both parties accountable for adhering to that direction. At a minimum, the Networks and State agencies should be held accountable for collaboration in the following four areas:

- ▶ ***Sharing facility-specific data.*** Such data are important vehicles for facility self-improvement. But they also can be useful (if not necessarily determinative) in informing State on-site surveys.
- ▶ ***Sharing State survey results.*** Similarly, results of the State surveys can be helpful to the Networks as they carry out their quality improvement efforts and as they address specific complaints involving individual facilities.
- ▶ ***Working together in addressing complaints.*** To help protect patients, the Networks, and State agencies should agree on when to make referrals to one another involving complaints. The pilot efforts we called for earlier can be helpful here.
- ▶ ***Consulting one another on areas of expertise.*** States and Networks both need to be valued for their perspective and expertise. Networks could help surveyors target facilities for surveys and help monitor and correct deficiencies involving the quality of care. Similarly, States could help Networks enforce minimums and identify regional trends. To make sure this occurs, HCFA should establish guidelines for when Networks and States should solicit the advice or assistance of the other.

One way in which HCFA can facilitate collaboration between the Networks and States is to convene forums in which HCFA, Network, and State officials come together to discuss the approaches to collaboration, the barriers that inhibit them, and actions that might be taken to overcome such barriers. The forums could also provide a good venue

to showcase promising approaches to collaboration that some Networks and States have already undertaken.

2b. HCFA should foster greater accountability of the Networks.

Develop, with input from the Networks, a system for performance-based evaluations of the Networks. This system would have to be established from the ground up since no such system is in place now. The current evaluations of Network are rudimentary, more of an accounting of activities than an evaluation of performance. We call for a reinvention of this entire approach in a way that minimizes routine annual reporting burdens and maximizes opportunities for substantive assessment and continuous improvement.

We suggest that, at least at the start, this reinventing effort focus on two central questions:

- ▶ ***How effectively are Networks drawing on standardized performance data to improve the overall clinical performance of facilities in their region and to ensure that poor performers meet minimum standards of care?*** Given the development of increasingly sophisticated clinical performance measures for facilities, it is reasonable to use them as key references in assessing the Networks' own performance. HCFA has moved in this direction with the Medicare Peer Review Program. It would appear to be timely to do the same for Networks.
- ▶ ***How effectively are Networks using a complaint system as a quality-of-care safeguard?*** The template we developed offers eight specific elements that can be examined to help answer this question.

As HCFA puts in place a performance-based evaluation system, it should give the Networks increased flexibility in how they use their resources. Such flexibility should enable Networks to develop improvement projects, intervention strategies, educational efforts, and other initiatives that are most pertinent to their region. The aim should be to find reasonable ways of holding Networks more accountable for results that make a difference in patient care while giving them added discretion in tailoring their efforts to the needs and characteristics of their regions. Providing Networks with the added flexibility we call for need not preclude developing a nationwide quality improvement project that all Networks participate in, if the rationale for that effort were sufficiently compelling.

Increase public disclosure of information on the Networks. As HCFA proceeds in developing an evaluation system as we call for above, it should also develop a core set of information on Network activities and performance that would be readily available to the public, preferably on the Internet — either on HCFA's own web site or on the Networks' web sites or posted in facilities. Such disclosure can be particularly important in helping the media, advocates, patients, and other interested parties understand how Networks use

performance data to improve dialysis care and of how they handle complaints. In the process, it reinforces the point that publicly-funded Networks are accountable to the general public as well as to HCFA.

2c. HCFA should foster greater accountability of the State survey agencies.

Establish a means to periodically assess the State surveys. One way HCFA could better assess the State surveyors is to observe more State surveys. This provides HCFA with the opportunity to provide direct feedback to surveyors and can be more instructive and timely than validation surveys. However, because of the technical nature of these surveys, it may be difficult for HCFA personnel to develop and maintain the expertise to constructively assess State surveys. In this regard, HCFA should consider developing a small group of contracted, experienced dialysis surveyors that it could draw upon to periodically observe State surveys as well as to investigate complaints as needed. For years, HCFA has relied upon a panel of contracted psychiatric surveyors to survey psychiatric hospitals. A similar mechanism could be used for the oversight of dialysis facilities.

Increase public disclosure of information on the State survey agencies. Disclosing information about the activities and performance of the State survey agencies is just as important as for the Networks. Particularly relevant would be information on the number of surveys conducted, the specific facilities surveyed, the type of deficiencies found, and the corrective actions taken. As with the Networks, HCFA could post this and other pertinent information on its own website or call for the States to post it on their own or even post it within the facilities as is the case for nursing homes.⁷⁹

COMMENTS ON THE DRAFT REPORT

We received comments on the two draft reports from HCFA and three additional outside parties: the Forum of the End Stage Renal Disease Networks, the Association of Health Facility Survey Agencies, and the American Association of Kidney Patients. Based on the comments we changed one recommendation and made several technical changes to the report. We include the complete text of the comments in appendix C. Below we summarize the comments and, in italics, we offer our responses.

HCFA Comments

HCFA generally supported our findings and recommendations and responded by submitting a detailed action plan. The action plan outlines HCFA's commitment to collect and disclose facility-specific performance data, increase on-site surveys, revise the Conditions for Coverage, strengthen the complaint process, and explore ways to implement a system to monitor adverse events. HCFA indicated that it intends to establish minimum performance standards for some clinical outcomes. HCFA did take issue with our recommendation to require joint Network-State initial certification surveys of facilities. HCFA also expressed concerns with assessing patient satisfaction, given a likely low response rate.

We find HCFA's detailed action plan to be a positive step toward strengthening the system of oversight for dialysis facilities. We caution HCFA not to include specific performance measures or minimum thresholds within the Conditions for Coverage. This will prevent timely updates as scientific knowledge advances. We believe that measures with minimum thresholds would be more aptly laid out in provider agreements with facilities. With regards to HCFA's concern about joint Network-State surveys, we revised the recommendation to state that HCFA should first conduct pilot tests to determine the effectiveness of this approach rather than requiring it. We recognize the shortcomings of such an approach, but we maintain that initial certification surveys offer a less threatening environment compared to a for-cause survey. Thus, Networks and States may find it easier to work together. We also think initial certification surveys are a good opportunity for the facility to meet both the Networks and the States before a problem arises. We encourage HCFA to move forward with assessing patient satisfaction even given the likelihood of low response rate. Finally, we want to further stress that HCFA release any and all facility-specific data that it collects to the public.

Forum of the End Stage Renal Disease Networks Comments

The Forum agreed with the majority of our findings but expressed concerns over several of our recommendations. The Network took issue with our finding that Networks rarely target poor performing facilities. It emphasized that Networks and States approach such facilities in different ways and both approaches are valuable. It cautioned against

specifying outcome targets in the Conditions for Coverage. The Forum raised concerns that efforts to monitor adverse events, patient satisfaction, and the public release of performance data may undermine the collegial role of the Networks. It suggested that initial certification surveys may not provide the best opportunity for joint Network and State surveys and suggested instead joint surveys of poor performers. It also took issue with our recommendation for developing a performance-based evaluation mechanism for the Network without a similar requirement for the States. Finally, it pointed out the Networks' role in monitoring transplant centers was not addressed.

We recognize that some Networks are targeting poor performing facilities, but our evidence shows that many Networks are not and that many do not have reliable facility-specific data to identify such facilities. We want to reiterate that the Networks and States both have responsibilities to ensure minimums and to improve the overall performance. It is not feasible at this time for the Networks to work exclusively in a non-punitive manner. We believe that the Texas example presented in our second report demonstrates that Networks and States can work in both realms, each with their respective emphases. We agree that joint Network-State surveys of poor performers may be valuable and may be an option that HCFA would want to test along with joint initial certification surveys. Given the emphasis of the Networks on quality improvement and the States' emphasis on enforcing minimums, we think that it is feasible to hold the Networks accountable for improving the performance of their facilities. We call for States to be held accountable for their role in enforcing minimums. Finally, we agree that the oversight of renal transplant centers is important, but that issue was beyond the scope of this inquiry.

Association of Health Facility Survey Agencies Comments

The Association of Health Facility Survey Agencies (AHFSA) agreed with the majority of our findings and recommendations, but indicated that we failed to provide any discussion of funding issues. Specifically, it called for additional funding for States to conduct more surveys. AHFSA also offered several additional recommendations that provide more operational approaches to our recommendations. It supported the notion of greater collaboration between the Networks and the States, the public release of facility-specific outcome data, and called for the Conditions for Coverage to require reporting of adverse events to the States.

We acknowledge in the report that competing budget demands is a major reason for the lack of surveys and recognize that many of recommendations will require additional funds. We address the concern about funding of the State agencies by calling for HCFA to determine an appropriate minimum cycle for conducting surveys. HCFA itself addressed this issue in its comments by noting that the President's Budget for FY 2001 calls for a substantial increase in funding for ESRD surveys. However, our recommendations require more than just additional funding — they also require strong leadership on the part of HCFA.

American Association of Kidney Patients Comments

The American Association of Kidney Patients (AAKP) strongly agreed with our recommendations and believed that our recommendations could result in better care for patients. AAKP pointed out its own concerns with the variability among Networks and States. It believes that the greater accountability we call for will lead to more consistent performance across Networks and States. AAKP also highlighted HCFA's current efforts underway to release performance data publicly and asked us to ensure that funding to implement our recommendations does not come at the cost of funding patient activities.

We are pleased to receive such strong support from AAKP which represents the patients that we aim to protect. In our report we acknowledge HCFA's effort to release performance data to the public and we believe it is a step in the right direction. Furthermore, we underscore AAKP's point that funding for oversight activities should not jeopardize patient care.

Methodology

HCFA

We interviewed HCFA officials responsible for the ESRD program at both the Central Office and the four lead ESRD regional offices (Boston, Kansas City, Dallas, and Seattle.) This included all the project officers for the Networks and HCFA officials involved with the State survey and certification programs. We gathered information on how HCFA evaluates the Networks and State agencies, their perceptions on the strengths and weaknesses of the program, and any recommendations they had for improving the oversight of dialysis facilities.

ESRD Networks

We conducted a mail survey of all 18 Networks to gather information on the types of performance data Networks use and collect, on how they handle complaints and adverse events, and how often they conduct on-site surveys. All 18 Networks responded. In addition to our survey, we received and analyzed the following documents from all the Networks: 1997 annual reports, 1998 annual reports, and 1998 responses to complainants.

We selected nine Networks to participate in telephone interviews. We chose at least two Networks from each of the four lead HCFA regions. Network staff and board members participated in the interviews, which covered topics related to the oversight of facilities such as quality improvement projects and other sources of performance data, complaint procedures and trends, and their relationships with HCFA and State agencies. We also selected two Networks for site visits lasting several days. These visits included interviews with staff, board members, patients, and renal professionals. While on-site we examined their complaint files. Three additional Networks received site visits that involved discussions with Network leadership about oversight in general.

State Survey Agencies

In order to gain information on the State agencies we analyzed HCFA's On-line Survey, Certification and Reporting System (OSCAR) to determine the frequency with which State agencies conduct Medicare certification and complaint surveys of ESRD facilities which includes both transplant facilities and dialysis facilities. We pulled two data sets from the system: one in May 1999 and one in August 1999. We analyzed these data sets using SAS and Excel software programs. In addition, we interviewed five State survey agencies. We also observed a dialysis facility survey.

Stakeholder Interviews

We interviewed several representative of organizations involved with dialysis issues. These organizations included professional groups, consumer groups, Federal agencies, and Federal contractors.

Literature Review

Throughout our evaluation, we reviewed various documents including statutes and regulations, Federal agency documents, policy reports, media articles, and scientific journal articles.

Major Sources of Clinical Performance Data for ESRD

Below we highlight several of the major sources of performance data for dialysis facilities.

HCFA's Clinical Performance Measures Project. Since 1994, with the help of the Networks and facilities, HCFA has collected a set of measures on a national sample of patients. In 1999, the set included 16 measures such as urea reduction ratio, Kt/V, hematocrit, hemoglobin, and type of vascular access. Facilities abstract the measures from patient medical records and Networks validate a sample of the data. HCFA disseminates aggregate measures at the national and Network level to the renal community and the public. The sample does not allow facility-specific analysis.

Medicare Billing and Enrollment Data. HCFA claim and administrative forms are a rich source of information on patients and facilities, such as patient hematocrit levels, urea reduction ratios, and mortality. Since 1996, HCFA has used this data to generate confidential facility-specific reports on anemia management for its National Anemia Cooperative Project. A few Networks reported using the anemia data to monitor facility performance and to identify facilities in need of interventions. HCFA currently uses these data to generate various facility-specific reports for facilities, Networks, States, and the public.

United States Renal Data System. Funded by the National Institutes of Health and partially funded by HCFA, this database compiles numerous data sources on renal patients, most of which come from Medicare billing data. Each year, an annual data report is disseminated to the public that provides trend information at the Network and national level. Previously, the USRDS generated confidential, facility-specific standardized ratios for mortality, hospitalization, and transplantation for facilities, which have been helpful in identifying regional problems in the quality of care. These reports are now being generated by HCFA. Most Networks reported that they use the USRDS methodology, or one based on it, to calculate their own standardized mortality ratios for facilities. A few Networks reported that they use the facility-specific ratios generated by USRDS to identify poor performers.

National Surveillance of Dialysis Associated Disease. This voluntary survey, started in the early 1970s by the Centers for Disease Control and Prevention, monitors infectious disease rates, such as hepatitis B, within facilities. It also collects facility-specific information on vaccination rates, vascular access, staffing ratios, and reuse of hemodialyzers. The data are disseminated to the public showing trends at the Network and national level. Every Network, except one, reported that they use these data to help determine future topic areas for quality improvement projects, to provide baseline data,

and/or to identify poor performers. These data are not readily available to the public or the States.

Network Databases. Networks maintain their own databases that vary from Network to Network. Some of the elements Networks collect on their own and some they obtain from the databases listed above. A few Networks disseminate confidential facility-specific reports to facilities. Network data is not regularly available to HCFA, States, or the public.

Comments

In this appendix we include the full text of comments of the parties that responded to our two draft reports. We present them in the following order:

HCFA

Forum of the End Stage Renal Disease Networks

Association of Health Facility Survey Agencies

American Association of Kidney Patients



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

DATE:

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle *Nancy-Ann DeParle*
Administrator, Health Care Financing Administration

SUBJECT: Office of Inspector General (OIG) Draft Report, "External Quality Review of
Dialysis Facilities, A Call For Greater Accountability" (OEI-01-99-00050) and
"Two Promising Approaches" (OEI-01-99-00051)

Thank you for conducting a thorough review of the external quality oversight of dialysis facilities in the United States and the roles played by the Health Care Financing Administration (HCFA), the State survey agencies, and the End Stage Renal Disease (ESRD) Networks. HCFA welcomes the report's findings and views the findings as an opportunity to make the changes necessary to improve the oversight and quality of care in dialysis facilities participating in the Medicare program. We are committed to working with the State survey agencies and the Networks to ensure that dialysis patients receive high quality care.

Our efforts to improve performance of the dialysis facilities have had some measurable success. For example, between 1994 and 1998 the percentage of ESRD patients with adequate hematocrit (red blood cell) levels increased from 55 to 83 percent. Additionally, in the same time period, the percentage of patients receiving adequate dialysis increased from 49 to 74 percent. We also know from the U.S. Renal Data System, a joint HCFA and National Institutes of Health project, the one year mortality rates for dialysis patients decreased from 24.9 deaths per 100 patient years in 1990 to 22.8 in 1997.

These improvements are due in part to the leadership role HCFA took beginning in 1994 to develop clinical indicators that assess the quality of care for dialysis patients. This effort is now known as the Clinical Performance Measures Project (formerly the National/Network ESRD Core Indicators Project). HCFA, through the ESRD networks, collects clinical indicators on a national sample of dialysis patients in the areas of adequacy of dialysis, anemia management, and serum albumin (a protein in the blood that is an indicator of the patient's overall health). These data are collected, analyzed and described annually in a detailed report, the *ESRD Clinical Performance Measures Project Annual Report*. This report is distributed to all dialysis providers for their use in identifying opportunities for improvement. Using this national sampling approach, we have documented improvement every year in the number of dialysis patients achieving the benchmarks for these clinical indicators since 1994.

Page 2 - June Gibbs Brown, Inspector General

We have also undertaken steps to begin collecting facility-specific data, something your reports advise HCFA to do. In 1998, HCFA directed the development of 16 clinical performance measures that we are collecting from a sample of facilities this year. This effort was initiated to implement a provision in the Balanced Budget Act of 1997 that requires HCFA to measure and report the quality of renal dialysis services. The 16 clinical measures are similar to those of the Core Indicators Project described above, with the addition of measures for evaluating vascular access (the point of access to the dialysis patient's blood stream). In 1999 this work was merged with the Core Indicators Project and the combined project is known as the ESRD Clinical Performance Measures (CPM) Project. The CPM Project is part of a larger ESRD Core Data Set that is under development. Through the ESRD Core Data Set, we are striving to determine and report accurate, meaningful facility-specific performance measures that will allow comparisons across dialysis centers and will ultimately increase facility accountability and patient choice. Facility-specific data profiles have been developed for the use of State Survey Agencies.

Despite our progress in improving the quality of care, there continue to be weak performing dialysis facilities. However, the Networks and States are working aggressively with these dialysis facilities to improve their care. We also intend to publish in early 2001 a proposed rule on new conditions for coverage for dialysis facilities that will strengthen requirements. In addition, the President's FY 2001 budget asked Congress to dramatically increase the funding level for surveys of ESRD facilities from \$2.2 million to \$6.3 million. By increasing the funding level, Congress would enable us to decrease the time between surveys from every six years to every three years and increase the number of surveys from 956 to 1,847 in FY 2001.

Our response to your comments, including HCFA's agency action plan and one technical comment, is attached.

Attachment
Agency Action Plan

**EXTERNAL QUALITY REVIEW OF DIALYSIS FACILITIES
A CALL FOR GREATER ACCOUNTABILITY
AGENCY ACTION PLAN**

RECOMMENDATION 1. HCFA should hold individual dialysis facilities more fully accountable for the quality of care.

1.a. HCFA should revise the Medicare Conditions for Coverage for dialysis facilities so that they serve as a more effective foundation for accountability.

Strengthen the accountability of the dialysis facility governing body.

- HCFA agrees with this recommendation and will prepare a comprehensive proposed rule to revise the current ESRD conditions for coverage. The proposed rule would require facilities to collect and report performance measures so that HCFA can monitor the quality of renal dialysis services provided under Medicare. The governing body of the facility would be responsible for the collection and reporting of patient care data to HCFA. Increased emphasis on specific health and safety standards such as water quality and infection control, would be included also. HCFA expects to publish this proposed rule in early 2001.
- Under the conditions for coverage rule, HCFA will propose that a facility's governing body be held accountable for the development and monitoring of a quality assessment and performance improvement program (QAPI). The purpose of a QAPI program is to ensure that the ESRD facility focuses on continuous improvement of processes of providing health care services to meet the needs and improve the outcomes for dialysis patients rather than to rely solely on detection and correction of problems. The proposed QAPI program would require each facility to develop, implement, maintain, and evaluate an effective, data-driven program, under which facilities would collect and report clinical outcomes information to HCFA. We intend to establish minimum performance standards for certain clinical outcomes, such as adequacy of dialysis, nutritional status, anemia management, and other appropriate criteria. HCFA would also propose that facilities which fail to meet minimum performance criteria be required to take corrective actions to improve performance.

Reinforce accountability of dialysis facility medical director for patient care.

- HCFA concurs with this recommendation and will revise the existing procedures and interpretive guidelines that State survey agencies use to survey dialysis facilities. The survey procedures and interpretive guidelines will be revised in 2000 to reinforce accountability of the physician director for patient care
- Currently ESRD regulations hold the physician director accountable in 5 specific areas of patient care:- participation in the selection of a suitable modality for each patient; assuring adequate training for dialysis nurses and technicians; assuring adequate monitoring of all patients and the dialysis process (including home dialysis patients); assuring the development and availability of patient care policies and procedures, including types of dialysis used in the

unit, hepatitis prevention and procedures, and a disaster preparedness plan; and assuring that home dialysis training materials are available if the unit offers home dialysis training.

Require facilities to electronically report standardized performance measures determined by HCFA.

- HCFA has already begun to take steps that will implement this recommendation. Under a contract with PRO-West, HCFA developed 16 clinical performance measures (CPMs) in the areas of adequacy of hemodialysis, adequacy of peritoneal dialysis, anemia management and vascular access. The collection of these CPMs was pilot tested in 1999 by the ESRD Networks using a national sample of dialysis patients. In 2000, the Networks will again collect these CPMs on a national sample of patients. Importantly, HCFA also will collect the CPMs from a sample of dialysis facilities in 2000.
- As the OIG Report points out, we are developing the computer infrastructure that will electronically link dialysis facilities, Networks and HCFA. The proposed ESRD conditions for coverage rule would require facilities to electronically report data, including the 16 CPMs, to HCFA. The facilities would use a computer system, the Vital Information System for Improvement of Outcomes in Nephrology (VISION) to enter data and transmit it to HCFA. VISION is scheduled for implementation in January 2001.

Require facilities to conduct their own Quality Improvement program.

- As noted above, HCFA will be proposing a revised conditions for coverage rule that will require each dialysis facility to develop and monitor its own quality assessment and performance improvement program (QAPI). This program may include clinical measures such as adequacy of dialysis, nutritional status, anemia management, standard mortality data, emotional and social well-being, and rehabilitative status. The QAPI will address the needs of each facility, and foster a culture of continuous quality improvement within the facility.

Require facilities to establish internal systems for identifying and analyzing the causes of medical injuries and medical errors.

- HCFA agrees that internal tracking systems have the potential to help identify problems quickly so that corrections can be made promptly and patients protected. In recognition of the President's announcement in support of a nationwide system of medical error reporting that is State-based, we will explore the feasibility of using this system for ESRD facility oversight. In addition, under the proposed ESRD conditions for coverage rule, HCFA will encourage facilities to have ongoing error reduction programs in place as part of their Quality Assessment and Performance Improvement Program.

Require dialysis facilities to monitor patient satisfaction.

- HCFA concurs, and through the conditions for coverage rule, would propose the collection of

patient satisfaction information as a reporting requirement. However, we have some concern about the response rate for patients on chronic dialysis and the validity of the results. The response rate for ESRD patients in the latest Consumer Assessment of Health Plans (CAHP) survey was only 50 percent, whereas the rate for the general Medicare population was over 80 percent. CAHPs is a HCFA survey that asks Medicare beneficiaries questions about satisfaction with their Health Maintenance Organization (HMO). The results are used to evaluate HMO performance. Given our concerns with the response rate, we will examine ways to monitor patient satisfaction under the QAPI program that all dialysis facilities will be required to implement under the proposed rule.

1.b. HCFA should use facility-specific performance measures to encourage facilities to improve the quality of care and to help ensure facilities meet minimum standards.

Identify a core set of performance indicators to collect regularly on all patients from facilities.

- HCFA concurs with this recommendation. In 1994, HCFA took a leadership role in developing clinical indicators to assess the quality of care for dialysis patients. Through the ESRD Networks, we have collected clinical indicators/measures on a national sample of dialysis patients in the areas of adequacy of dialysis, anemia management, and serum albumin; vascular access measures were added in 1999. The data are collected annually and a detailed report describing the findings at the national and regional level is disseminated to all dialysis providers for their use in identifying opportunities for improvement. A national patient sampling approach, stratified by ESRD Network area for the hemodialysis patient sample, was chosen initially because of the workload burden on dialysis facilities and the ESRD Networks in using a hard copy reporting system.
- Using this national sampling approach, we have been able to document improvement in the number of dialysis patients achieving the benchmarks for these clinical indicators in every year since 1994. Dialysis providers have found these measures and the annual distributed report of findings to be a valuable tool in assisting them to improve care. By 2001, we plan to collect these measures on all patients from all providers. This will provide HCFA with facility-specific data that can be used to assess facility compliance, to assist facilities in improving care, and to report facility-specific performance to the public. We are developing a computer system, VISION, that will allow dialysis facilities to collect and report these data electronically to HCFA. We anticipate pilot testing this electronic system in 2000 with implementation by all facilities in 2001.
- The efforts described directly above are part of the larger ESRD Core Data Set that HCFA is developing. Dialysis facilities will be required to collect the Core Data Set, including the 16 Clinical Performance Measures, for all patients and report regularly through VISION. The first draft of Core Data Set elements is expected to be ready for stakeholder comment by July 2000.

- We also would propose requiring facility-specific measures to increase facility accountability to HCFA in the ESRD conditions for coverage regulation such as, adequacy of dialysis, nutrition, anemia management, standardized mortality ratios, quality of life and rehabilitative status. HCFA will propose to establish minimum performance levels in the areas listed above and have this information reported by each facility on a regular basis.
- HCFA is using these facility-specific measures to create profiles of facilities which will include composite scores that rank facilities within the State. The profiles also will include data and information related to patient health and safety. This initiative is underway.
- HCFA will hold facilities accountable by requiring them to develop performance improvement projects to meet minimum federal standards.

Disseminate comparative facility-specific reports to facilities, Network, State survey agencies, and the public containing all of the performance indicators in the core set.

- HCFA supports this recommendation. We are currently working on developing an Internet based system to disseminate facility-specific reports to the public, similar to our Nursing Home Compare Site. A first set of facility-specific measures is being developed. These measures will describe facility characteristics and the quality of services provided that can be reported to the public.

This first set of measures will be based on existing HCFA data and will primarily describe the facility, such as the name and address of the facility, the type of dialysis treatments offered by the facility and number of hemodialysis stations. This first set of measures will also include several clinical measures, such as the percentage of patients who receive adequate dialysis, the percentage of patients whose anemia was corrected, and the actual, compared to expected, patient survival rate. We anticipate that these first reports will be available to the public by the end of 2000. We plan to add additional measures to these reports as we collect data electronically from the dialysis facilities.

- Note that, in order to disseminate comparative facility-specific reports, HCFA will need to resolve several concerns including: issues relating to privacy restrictions on the release of data; issues relating to privacy restrictions regarding release of physician-specific data; and issues of what data can and will be released to specific groups and to the public without breach confidentiality.

1.c. HCFA should strengthen the complaint system for patients and staff.

Work with the Networks and the State survey agencies to establish an effective complaint system for dialysis patients and staff.

- HCFA concurs with the 8 elements presented in the report as a template for an effective complaint system: Accessibility, Objectivity, Investigative Capacity, Timeliness,

Responsiveness to Complainants, Enforcement Authority and Follow-up, Improvement Orientation, Public Accountability. We have formed a workgroup to review the complaint process to make it easier and more responsive to dialysis patients, and a more manageable and integrated system for the Networks and State survey agencies. HCFA will also strengthen procedures for anonymous complaints to avoid the possibility of retaliation against patients.

- HCFA is developing a new regulatory basis for Network response to complaints that will support both more complete responses to complaints and alternative dispute resolution methods.

Conduct pilot projects to test ways in which the Networks and the State survey agencies could work together to create an integrated complaint system.

- HCFA agrees that pilot projects are most useful in developing a viable, structured complaint process. Networks have accompanied the State survey agencies occasionally on complaint investigations of dialysis facilities. HCFA will conduct pilot projects to develop an effective, integrated complaint process, as resources permit.

Develop a common instrument that facilities and others could use to assess patient satisfaction.

- During development of the proposed ESRD conditions for coverage rule, HCFA intends to explore the development of a patient satisfaction instrument. HCFA will review the patient satisfaction surveys that some dialysis facilities currently use and take into consideration the practical difficulties and potential burden on facilities that may result from requiring patient satisfaction information.

1.d. HCFA should enhance the role of Medicare on-site certification surveys.

Determine an appropriate minimum cycle for conducting Medicare certification surveys of dialysis facilities.

- HCFA agrees that there should be an appropriate minimum cycle for conducting Medicare surveys of dialysis facilities. The President's Budget for FY 2001 would substantially increase the funding level for surveys of ESRD facilities from \$2.2 million to \$6.3 million. This funding level would allow us to decrease the time between surveys from every 6 to every 3 years, and increase the number of surveys from 956 to 1,847 in FY 2001.

Require joint Network-State agency surveys for initial certification visits of dialysis facilities.

- HCFA disagrees that Networks and States should conduct initial certification surveys. As your report notes, the Networks are characterized by a collegial approach to oversight with a

focus on educating and improving performance. In contrast, the role of the State survey agencies is regulatory with an emphasis on investigating and enforcing minimum requirements. We believe that it is important to distinguish these roles during the initial certification surveys. These initial surveys are an important step in the process that allows new dialysis providers into Medicare to treat vulnerable beneficiaries. In addition, the Networks are not structured or funded, nor is it their mission to perform initial certification on-site visits of dialysis facilities.

1.e. HCFA should facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes.

- HCFA agrees that efforts should be established to work with Networks and States to identify, monitor, and institute improvement projects regarding serious medical injuries and "near misses" in dialysis facilities. The Renal Physicians Association, in partnership with the Forum of ESRD Networks, has formed a Patient Safety Committee to define the types of errors of concern in dialysis facilities. This committee is also considering developing a data collection tool that would allow the tracking of medical errors in dialysis facilities. HCFA intends to seek statutory authority that would allow us to apportion Medicare Trust Fund money for this data collection activity.

RECOMMENDATION 2. HCFA should hold the Networks and State survey agencies fully accountable for their performance in overseeing the quality of care provided by dialysis facilities.

2.a. HCFA should issue policy guidance delineating the distinctive roles of the Networks and State survey agencies in quality oversight and providing direction on how they should collaborate.

Sharing facility specific data.

- HCFA agrees that certain facility specific data held by the ESRD Networks should be shared with the States. To this end, HCFA is currently working with the Office of General Counsel to resolve issues stemming from section 1160 of the Social Security Act that deal with "Prohibition Against Disclosure of Information" by Networks.

Sharing State survey results.

- HCFA agrees that Networks would benefit from receipt of State agency survey findings and corrective action plans. To this end we will develop and promulgate a process to make survey findings more readily available to Networks. One option would be for HCFA to require State agencies to send survey results to Networks.

Working together in addressing complaints.

- We concur that a structured joint complaint process coordinated between the ESRD Networks and the State survey agencies is desirable. HCFA will conduct pilot projects in this area to develop an effective complaint process, as resources permit. In order to implement this task, HCFA will ensure that both Networks and States have critical information on complaints.
- HCFA has developed a system for reporting standardized complaint information by all Networks through the Standard Information Management System (SIMS) which became operational January 2000. The implementation of SIMS is the first step in developing an electronic system of reporting and following a complaint as it is processed.

Consulting one another on areas of expertise.

- HCFA agrees and is working to facilitate collaboration between Networks and States. As described in your companion report "External Quality Review of Dialysis Facilities, Two Promising Approaches," a cooperative relationship between the Network and State agency has been established in Network 14. In 1995, the Texas State legislature enacted a law requiring all dialysis facilities to be licensed in order to operate in the State. The legislation established a formal relationship between the State's Department of Health and the Network's medical review board who, together with the renal community, developed and implemented standardized performance measures for dialysis facilities.
- HCFA will establish specific guidelines for coordinating, monitoring, and reporting to build a more cooperative relationship between States and Networks, especially in the area of sharing expertise to further protect ESRD patients. In addition, as funding permits, we plan to convene forums in which HCFA, Network and State officials can discuss ways to partner to ensure quality care for ESRD patients.

2.b. HCFA should foster greater accountability of the Networks.

Develop, with input from the Networks, a system for performance-based evaluations of the Networks.

Network accountability efforts should focus, in part, on how the Networks are drawing on standardized performance data to improve the overall clinical performance of facilities in their region and to ensure that poor performers meet minimum standards of care.

- We agree with this recommendation. HCFA has begun discussions on how we can move the Networks to performance-based contracting such as that recently instituted for the Peer Review Organizations. We will continue pursuing this contracting mechanism and intend to have this process in place by 2002. As noted elsewhere in this report, HCFA will require

Networks to use standardized clinical performance measures to track and monitor facility performance, and to intervene with facilities that are poor performers.

Network accountability efforts should also focus on how effectively the Networks are using a complaint system as a quality-of-care safeguard.

- HCFA agrees that complaints should be a focus for Network accountability and the 8-step template proposed in the report is a good working model on which to build a structured complaint process. A workgroup is revising the ESRD Network Manual instructions to coordinate definitions and procedures with the State agencies to make the complaint process easier and more responsive.

Increase public disclosure of information on the Networks.

- HCFA will provide the public with more information about the role and activities of ESRD Networks through the Internet. We also intend to develop brochures about the ESRD Networks that would be available in facilities, at health fairs, and at other patient organization gatherings.

2.c. HCFA should foster greater accountability of the State survey agencies.

Establish a means to periodically assess the State surveys.

- State oversight for ESRD is unique because the survey process for dialysis facilities is technically and clinically complicated. HCFA will examine methods to increase onsite oversight of State activities. This will include reviewing the feasibility of increasing the number of observational surveys and using a contractor to assess the effectiveness of the State agency surveys.

Increase public disclosure of information on the State survey agencies.

- HCFA will explore methods for increasing the use of the Internet to publish survey results. We also will provide the public with more information about the role and activities of State survey agencies. The current patient information packet being developed for new ESRD patients will include information on the role and authority of State survey agencies.

Technical Comment

Page 42, footnote 43

The footnote on page 42 should be rewritten to change 15 months for nursing homes to 12 months, and to add Section 1819 of the Social Security Act to the statutory references.

FORUM OF END STAGE RENAL DISEASE NETWORKS

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May 18, 2000

June Gibbs Brown, Inspector General
Office of Inspector General
330 Independence Ave. S.W.
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Washington, D.C. 20201

Dear Ms. Brown,

The Forum of ESRD Networks appreciates the opportunity to comment on the reports of the Office of the Inspector General (OIG) entitled "External Quality Review of Dialysis Facilities, A Call for Greater Accountability" and "External Quality Review of Dialysis Facilities, Two Promising Approaches". The Forum Board of Directors, ESRD Network executive directors, and ESRD Network Medical Review Board chairs reviewed these reports. Many of us had the opportunity to interact with the OIG staff conducting the investigation, whom we found to be extremely knowledgeable and courteous. This response represents the synthesis of comments received from Forum and Network representatives, many of whom are physician volunteers. The reports are well researched and those involved in their preparation appear to have considered all resources. We found the reports to be quite perceptive and we agree with most of the findings of fact, although we have some concerns regarding the effective implementation of some of the recommendations.

We agree that the Conditions for Coverage must be strengthened and applied consistently throughout the country; however outcome targets for individual performance measures should not be specified in the Conditions of Coverage because of changing evidence-based medicine. Networks and state surveyors must use facility profiles to improve overall quality of care and assure that minimum standards are met. Facility-specific process and outcome data are already available and the Network role in quality improvement (QI) is well documented. The assessment of patient satisfaction and the documentation of adverse events are both very important areas that need attention and action by Networks and state surveyors. Care must be given, however, in the development of instruments and systems to address these two newer areas so as not to hinder the traditional non-punitive role of Networks to foster quality improvement and yet assure that patients are protected and standards of care are met.

We would like to offer the following comments for consideration by the OIG in the preparation of the final documents:

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1. Joint Initial Survey and Certification Activities

The OIG report concludes that ESRD Networks rarely target poorly performing facilities most in need of intervention. This is not entirely accurate; ESRD Networks do routinely work with poorly performing facilities. When poorly performing facilities are identified, ESRD Networks and state survey agencies may both be involved; however, the nature of the intervention may be vastly different. State survey agencies usually respond by conducting a site visit. Networks, because of personnel and resource limitations, respond with a variety of educational efforts, direct correspondence with facility leadership and occasionally with site visitation. Both approaches have been demonstrated to improve the quality of care and should continue to complement each other.

The OIG has made valuable contributions by advocating more cooperation between Networks and state agencies and by urging HCFA to give Networks the flexibility to use their limited resources in a way that can be tailored to address regional needs. Joint surveys to review poorly performing facilities may be an effective use of resources. However, we question the usefulness of joint surveys for initial survey and certification. At the time of the initial survey, very little exists at the facility in terms of records or programs for review and there is little demonstrated need for QI education or other actions Network staff might perform.

Initial, routine, and targeted facility surveys must be based on clear and documented criteria. Standards should be set that include input from all stakeholders. The selection process, review process and resources needed must be carefully considered before finalizing policies regarding on-site reviews.

2. Public Disclosure of Facility Information

The OIG report acknowledges that Federal regulations afford special liability protections for ESRD Networks. Federal regulations prohibit disclosure of grievance information, recognizing the importance of confidentiality protections for complaint investigations and peer review. Pressures for public disclosure must not dilute or supersede privacy laws and Federal regulations on confidentiality. Doing so would undermine the entire foundation of the ESRD Network organizations.

The efforts of the Consumer Information Workgroup, led by PRO-West, are not acknowledged in this report. In their initial recommendations to HCFA, PRO-West supported a minority opinion, advocating that facility specific outcome measures not be publicly reported at this time, due to questions concerning the validity and timeliness of the data, lack of case-mix adjustment, and the potential for “cherry-picking” of patients.

The Forum supports the responsible release of facility specific data that are proven to be valid, timely and presented at a level that is easily understandable by the ESRD patient community. If some of these data are collected through the Networks, validation strategies must be in place to assure their accuracy while preserving the non-punitive relationship between Networks and providers. Poorer performing providers will seek, rather than avoid, Network interventions to improve their public record.

3. Complaint System

The OIG noted the barriers to patients’ complaints and acknowledged the current lack of consistent definitions for types of inquires. Accurate definitions that describe the nature and level of complaint (i.e. inquiry, complaint, formal grievance) must be established for facilities, Networks, state surveyors and HCFA. This will foster a greater understanding of the relevant issues and achieve greater consistency in the response to patients’ concerns. Similar issues apply to complaints by dialysis facility staff. A more comprehensive system to reduce the fear of retribution (analogous to “whistle-blower” protections in other workplaces) is required.

4. Accountability of Networks and State Survey Agencies

The OIG report envisions a performance-based evaluation system with a goal of “holding Networks more accountable for results that make a difference in patient care...”. Networks (not state survey agencies) may be required to have their performance appraised by the degree to which they are able to effect performance improvements in dialysis facilities.

The OIG correctly states that Networks have limited authority to correct poor provider performance as documented by facility specific measures, yet later in the report the OIG explicitly recommends that improvement in facility outcomes be the yardstick by which Network performance is appraised. If Networks are held accountable for dialysis facility performance, they must have the authority and resources to effect change.

The OIG report does not advocate a performance-based evaluation system for state survey agencies. Rather, the states will have their work periodically assessed by a small group of experienced surveyors. State survey agencies have substantial power over dialysis facilities which, to date, has been inconsistently applied. They have the regulatory ability to invoke change and even close dialysis facilities. Paradoxically, the evaluation of the performance of state surveyors is not based on process or outcomes improvement of the facilities they have surveyed or on any sort of standardized instrument.

The Forum endorses the OIG’s advocacy for greater cooperation between Networks and state survey agencies, the OIG’s urging HCFA to give Networks the flexibility to use their limited resources in a manner that is tailored to regional needs, and the OIG’s calling for mechanisms to be developed for evaluating performance of Networks and state survey agencies. The Forum is concerned, however, that Networks, which hold the lesser power of the two oversight entities, will be evaluated based on the degree to which they can effect voluntary change by dialysis providers. If performance is the agreed-upon benchmark, it should be applied to both agencies. Perhaps a more suitable approach may be to hold both agencies accountable for having methods to promote process and outcome improvement, while not holding either agency directly responsible for the improvements themselves. Such an approach is more likely to foster more creative and innovative intervention activities that can be implemented without fear that failure will jeopardize future funding.

5. Transplantation

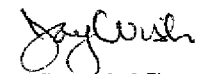
The OIG report focuses on the review of dialysis facilities but makes no mention of the Networks’ responsibility to work with renal transplant centers. Responsibility for oversight of transplantation programs must be articulated. Networks have established relationships with transplant centers, but the responsibility for transplant data collection and analysis was transferred to the United Network for Organ Sharing (UNOS) several years ago. UNOS falls short at evaluating program performance and providing interventions for process or outcomes improvement. It is currently unclear if any oversight is being provided to evaluate the quality of care provided to transplant patients. The Forum considers this a potentially dangerous lapse in accountability and one that should be addressed in this report.

In their QI-based intervention activities, Networks emphasize to providers that in order for quality to improve, the appropriate systems must be in place to collect, analyze, and respond to data so that processes can be evaluated in a way that will positively impact on outcomes. Facilities often respond that the resources required for QI (personnel and data systems) are expensive and they question whether this investment will pay for itself over the long term. Successful QI programs have demonstrated that quality is invariably cost-effective. Ironically, the ESRD oversight system is facing many of the same economic issues. Revising the current regulations and/or requirements for providers, Networks, and state survey agencies has the potential for improving performance but will also have a cost. Systems need to be created to effectively use as much already existing data as possible to provide the accountability recommended by the OIG reports. As requirements for data collection, transmission, analysis, and feedback increase, additional funding will be needed to support these efforts. Increased numbers of site visits in collaboration with state

surveyors will require that resources be identified to support staff travel, education and training. Without increased resources, the recommendations contained in the OIG reports have very little chance for successful implementation. However, in the long run, cost savings from improved patient outcomes (decreased hospitalizations and use of other costly resources) should make an improved quality oversight system an extremely sound investment.

The Forum of ESRD Networks recognizes the tremendous effort by the OIG to produce these reports and supports the development of systems to improve the care and quality of life for patients with end stage renal disease. We endorse the dual oversight model of Networks to promote QI in a non-punitive environment and of state survey agencies to hold providers accountable for adhering to standards of care established by the Conditions of Coverage. Inevitably the separation of those functions will blur as data collected by the Networks are used to promote provider accountability by triggering state survey activities or by release into the public domain, and as Networks and state survey agencies share facility-specific data to collaborate on intervention activities. Nonetheless, if the proper systems are established which clearly define, properly fund, and provide accountability for Network and state survey agency activities, this model has the greatest likelihood of achieving the goal of improving the outcomes of patients with ESRD by bringing provider performance to a higher level. The success of innovative Network models of quality oversight as described in the "Two Innovative Approaches" report underscores the importance of allowing the Networks, through their Scope of Work, to exercise the discretion to tailor their programs to the needs and resources of the region and not using a "one size fits all" approach to the contract deliverables. The heart and soul of the quality agenda of each Network, its Medical Review Board (MRB), is a voluntary organization composed of renal professionals and patients from the region. Care must be taken not to straightjacket and alienate these MRBs with a restrictive and inflexible national quality agenda that stifles creativity and does not exploit the local expertise or address the unique process issues of a region. The Forum is proud of the achievements of the Network system to date and hopes that the OIG reports will be the stimulus for a reengineering that promotes even greater success.

Sincerely,



Jay B. Wish, MD
President



Association of Health Facility Survey Agencies

May 9, 2000

The Honorable June Gibbs Brown
 Inspector General
 Department of Health and Human Services
 ATTN: Michael Mangam
 330 Independence Avenue
 Room 5246 Cohen Building
 Washington, D.C. 20201

Dear Inspector General Brown:

Thank you for the opportunity to review the two draft inspection reports on the external quality review of dialysis facilities. The report is generally well presented. We do note that while the report points out and underscores what state agencies (SAs) need to be doing and need to improve in doing, there is a stark absence of any mention of the direct tie to funding levels.

We do agree with the findings and recommendations presented in the report. Further, we offer the following for your consideration:

- HCFA should secure appropriate additional funding to states for increased survey activity of ESRDs and implementation of the report recommendations.
- The ESRD Conditions of Participation (CoPs) should include the requirement to report medical injuries to SAs and specific data collection requirements for facilities to analyze and develop plans to fix the problem that caused the medical injury.
- Delete reference to announced surveys on page 7 of the OIG report.
- HCFA should clarify the role of the networks and the SAs, and require joint surveys/complaint investigations under certain circumstances.
- Networks and the SA should forward copies of all complaints and their results to each other.
- Networks should work collegially with facilities on identification of problems, however, if little or no improvement is seen, the Network should be required to notify the SA.

The Honorable June Gibbs Brown
 Inspector General
 May 10, 2000
 Page 2

- Require the SA to report CoPs not in compliance to the Network and require the Network to work with the facility in developing corrective action.
- Require HCFA to publish facility specific data on the Web that includes survey results, transplantation rates, adequacy rates (Kt/V) and Hct average levels for the facility.
- Require facilities to send satisfaction surveys to patients and return them to the Network and SA.
- Require facilities to, as part of patient rights, inform patients of the name and address of the Network and the SA in order to lodge complaints and post the name and address of the Network and the SA on a bulletin board in the waiting room.
- HCFA should develop specific criteria by which to consistently evaluate SAs and Networks and ensure implementation is consistent through its Regional Offices.
- New CoPs should include more QA components other than re-use and clarify more succinctly the accountability for the medical director.

Again, we appreciate this opportunity to comment. Please be assured of our willingness to work for improvements in quality of care for ESRD patients.

Sincerely,



Catherine Morris, President
 Association of Health Facility Survey Agencies

cc: George Grob
 Elise Stein



The Voice Of All Kidney Patients

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May 13, 2000

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Dear Ms. Brown:

Thank you for the opportunity for the American Association of Kidney Patients to respond to the draft inspection reports on the external quality review of dialysis facilities. As the only national kidney patient association directed by patients for patients, we realize the important need to ensure quality of care and access for all dialysis and potential dialysis patients.

First of all we commend the Office of Inspector General for assessing the external quality review mechanisms currently in place and reviewing their strengths and weaknesses. We agree that there are inconsistencies in the program and are pleased by the amount of information your office has evaluated.

Medical Advisory Board

Eli Friedman, MD
Chairman

AAKP agrees with your recommendations that 1.) HCFA should hold individual dialysis facilities more fully accountable for the quality of care they provide and 2.) HCFA should hold the Networks and State survey agencies more fully accountable for their performance in overseeing the quality of care provided by dialysis facilities. We believe both of these recommendations could lead to better patient health outcomes and longevity. We strongly suggest that national standards be implemented to ensure that all Networks, State Survey Agencies and dialysis facilities follow the same guidelines.

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Thomas Peters, MD
Jay Wish, MD

With regard to the Networks and State Survey Agencies, AAKP has always remained concerned about the inconsistencies found throughout the ESRD Network system. While some Networks do outstanding jobs in developing continuous quality improvement programs, patient assistance and professional accountability, many Networks do not. With guidelines in place, we could expect greater reliability in how the two groups perform in the renal community.

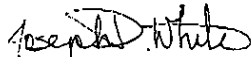
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We wish to bring two points to your attention regarding your recommendations. You suggest there be a reporting mechanism for public dissemination of facility performance data. At this time, HCFA and Pro-West, with input from the renal community, are developing ways to report data to the general public. The availability of such data is scheduled for release by the fall of 2000. Second, though we realize your recommendations are not based on availability of Medicare funding, we are cognizant of the costs associated with such recommendations. We would encourage you to ensure that such funding does not come at the cost of current patient activities.

Thank you for the opportunity to respond to your excellent report. If you wish to discuss this in further detail, please do not hesitate to contact Kris Robinson, executive director, at 800-749-2257.

Sincerely,



Joseph D. White
President

Endnotes

1. Section 1881(c) of the Social Security Act.
2. 42 C.F.R. sec. 405 subpart U.
3. Currently, there are about 19 States with licensure laws. Glenda M. Payne, "Licensed, Certified, Accredited: What are the Differences for the Dialysis Unit?" *Nephrology News and Issues*, September 1999, 47.
4. In order to qualify, individuals must be fully insured under Social Security or be a dependent of someone who is. In 1996, about 8 percent of individuals with ESRD who needed treatment did not qualify for Medicare coverage. U.S. House of Representatives, Committee on Ways and Means, *1998 Green Book*, (Washington, DC: Government Printing Office), 162.
5. 42 C.F.R. sec. 413.174.
6. For media accounts see: Kurt Eichenwald, "Death and Deficiency in Kidney Treatment," *The New York Times*, December 4, 1995, 1; K. Eichenwald, "At Big Kidney Chain, Deals for Doctors, Ruin for Rivals," *The New York Times*, December 5, 1995, 1; K. Eichenwald, "Making the System Work in Kidney Patients' Favor," *The New York Times*, December 6, 1995, 1; Wayne Woolley, "Dialysis Clinic Accused of Fraud: Ex-administrator Says Sinai Facility Had too Many Patient Deaths, Safety Infractions," *The Detroit News*, January 1, 1998, C1; Patrick O'Neill, "Complaints lead to look at dialysis centers," *Portland Oregonian*, October 19, 1998, B1; Patrick O'Neill, "Patients Get Wrong Mixture in Dialysis," *Portland Oregonian*, February 13, 1999, D1; Patrick O'Neill, "Dialysis problems increasing, official says," *Portland Oregonian*, February 17, 1999, A1; Patrick O'Neill, "Nerves Fray for Dialysis patients Cost-Cutting and Ownership Changes Highlight a New Breed of Treatment Centers," *Portland Oregonian*, February 23, 1999, B1.
7. It is a common practice for facilities to reuse hemodialyzers. Facilities that reuse must adhere to special protocols to prevent the spread of blood borne diseases.
8. U.S. Renal Data System, *USRDS 1999 Annual Data Report*, National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, April 1999: 26.
9. Health Care Financing Administration, Department of Health and Human Services, *Highlights from the 1999 Clinical Performance Measures Project*, <http://www.hcfa.gov/quality/3m.htm>, printed February 7, 2000.
10. Ibid.

11. William M. McClellan et al., “Variable Mortality Rate Among Dialysis Treatment Centers,” *Annals of Internal Medicine* 117 (1992): 332-336; William M. McClellan et al., “Facility Mortality Rates for New End-Stage Renal Disease Patients Implications for Quality Improvement,” *American Journal of Kidney Diseases* 24 (August 1994) 2: 280-289.
12. Jeffrey C. Fink et al., “Hemodialysis Adequacy in Network 5: Disparity Between the States and the Role of Center Effects,” *American Journal of Kidney Diseases* 33 (January 1999) 1: 97-104; Steven D. Helgersen et al., “Improvement in Adequacy of Delivered Dialysis for Adult In-Center Hemodialysis Patients in the United States, 1993 to 1995,” *American Journal of Kidney Diseases* 39 (June 1997) 6: 851-861; James A. Delmez et al., “Hemodialysis Prescription and Delivery in a Metropolitan Community,” *Kidney International* 41 (April 1992) 4: 1023-1028.
13. William M. McClellan et al., “Mortality in End-Stage Renal Disease Is Associated with Facility-to-Facility Differences in Adequacy of Hemodialysis,” *Journal of the American Society of Nephrology* 9 (October 1998) 10: 1940-1947.
14. Pushkal P. Garg et al., “Effect of the Ownership of Dialysis Facilities on Patients’ Survival and Referral for Transplantation,” *The New England Journal of Medicine* 341 (November 25, 1999) 22: 1653-1660.
15. Ibid, 1659.
16. *USRDS Annual Data Report*: 165-167.
17. *USRDS Annual Data Report*: Reference Tables, Table I.13.
18. Mark E. Neumann, “A Buying Slowdown?” *Nephrology News and Issues* July 1999, 30-31.
19. The composite rate is not routinely updated like the rest of Medicare payments. The composite rate was established in 1983. It was reduced by \$2 in 1986 and increased by \$1 in 1991. Recent legislation increased it by 1.2 percent in January of 2000, and another 1.2 percent increase will occur in January 2001.
20. This project was previously called the ESRD Core Indicators Project. In 1998, HCFA contracted with PRO-West, a professional review organization, to develop performance measures based on the National Kidney’s Foundation Dialysis Outcome Quality Initiative clinical practice guidelines. As a result, the previous clinical indicators under the Core Indicators Project were replaced with new but similar clinical performance measures.
21. *Highlights from the 1999 Clinical Performance Measures Project*.
22. ESRD Network of Florida (#7), *1998 Annual Report*.

23. ESRD Network of Texas (#14), *1998 Annual Report*.
24. For examples of Networks that collect facility-specific data see *1998 Annual Reports* for: The ESRD Network of New England (#1), Southeastern Kidney Council (#6), The Renal Network (#9/10), and ESRD Network of Texas (#14).
25. Social Security Act 1881(b).
26. In all of 1997 and 1998, Networks made only two recommendations to HCFA to sanction facilities.
27. If a patient health and safety issue is involved the only sanction that HCFA or the States can take is to terminate the facility from the Medicare program. Other types of sanctions, such as denial of payments or reduction of payments, can only be taken when the problem identified does not jeopardize patient health and safety. See 42 C.F.R. sec. 405.2180 and 405.2181.
28. Networks reported that HCFA, in one case in particular, did not support a Network's recommendation for sanction. As a result the Network felt powerless to resolve future problems because facilities in the area perceived that HCFA would not support the Networks. Another Network recently tried to avoid this situation by successfully encouraging a facility to voluntarily withdraw from the Medicare program rather than recommend sanctions to HCFA. However, HCFA reported that they viewed this approach as the Network trying to protect the facility since the provider can still run another facility elsewhere. Many Networks are now reluctant to take this approach, leaving the Networks with little they can do to enforce standards beyond applying peer pressure.
29. Social Security Act 1881(b) (8).
30. See <http://www.hcfa.gov/stats/pufiles.htm>
31. Office of Inspector General, "*Know Your Number*" Brochure: *Perspectives of Dialysis Patients*, OEI-06-95-00320, January 1997: 7.
32. HCFA, Network Manual, section 755.2.
33. HCFA has established complaints as a top priority for the State survey agencies; it lists complaints third out of 12 workload priorities for the States. Fiscal year 2000 State Survey and Certification Budget Call Letter, July 7, 1999.
34. In response to our survey, the 18 Networks reported referring 49 complaints to the State survey agencies in 1998.

35. Until recently there was no national database for Networks to log their complaint activity. HCFA recently developed a central database system for the Networks, the Standard Information Management System (SIMS), that should help standardize complaint information across all Networks and provide national information in the future. Most Networks publish data on their own complaints in their annual reports and some Networks even provide a breakdown by type. The Forum of ESRD Networks conducted a national analysis on complaints in its 1997 summary report that contains data from all 18 Networks. See Forum of ESRD Networks, *End Stage Renal Disease Network Program Annual Report Summary 1997*: 20-21.

36. In order to conduct this review, we grouped complaints into five categories. 1) technical issues involving clinical expertise of staff and/or water treatment etc., 2) service quality issues involving patient comfort such as temperature, waiting times, friendliness of staff, the number of staff available, etc., 3) educational/informational issues involving calls where individual are looking for answers to specific questions, 4) disruptive patient issues involving violent or misbehaving patients, and 5) unknown issues involving contacts that we could not discern their nature from the documents we reviewed. Some complaints fit into multiple categories and were counted as such. It is also important to note that the comprehensiveness of the complaint logs we received varied substantially. We do not intend for this analysis to provide concrete numbers but rather to demonstrate an overall trend.

37. One Network wrote a letter to HCFA documenting the lack of collaboration between the State and the Network. Northwest Renal Network (# 17), *Recommendations for Improvements in the States of DHS and ESRD Networks Cooperative Relationship*, September 1999.

38. Networks occasionally visit facilities to provide technical assistance, look into specific problems, or investigate complaints. However, HCFA does not fund them to perform routine on-site surveys.

39. Our analysis is of ESRD facilities that includes both dialysis facilities and renal transplant centers. According to *USRDS 1999 Annual Data Report* p. 165, there were 241 centers providing renal transplants in 1997. This number has been relatively stable over recent years. Our analysis also includes both initial surveys and recertification surveys.

40. The data shows that as of the May 1999, the average time since the last survey was 3.2 years for free-standing facilities and 4.2 years for hospital-based facilities. This suggests surveyors may be targeting free-standing facilities, which may be subject to less external oversight than hospital-based facilities.

41. An unpublished HCFA-funded study found a similar trend. The study showed that in 1993, 59.4 percent of free-standing facilities received a certification survey; in 1994 36.1 percent; and in 1995, 22.6 percent. The Lewin Group, Inc. and Johns Hopkins University, *Facility Accreditation and Certification for ESRD Study: Evaluation of the Effectiveness of the Current*

End-Stage Renal Disease Survey and Certification and the Potential of Integrating Private Accreditation,” unpublished draft May 30, 1997, for the Health Care Financing Administration.

42. Although we were unable from the data set we pulled from HCFA to determine the number of initial versus certification surveys, HCFA did provide us with the actual number of initial surveys conducted each year. We used the numbers of initial surveys provided by HCFA to calculate the number of recertification surveys and found that this backlog cannot be solely attributed to the recent growth in ESRD facilities. The number of initial surveys conducted each year increased only 24 percent since 1993, from 221 initials in 1993 to 273 initials in 1998. But we have seen a 72 percent decrease in the number of recertification surveys conducted each year since 1993. In 1993, over half of all facilities received a recertification survey. By the end of 1998, only 10 percent of all facilities received a recertification survey. At this rate of 10 percent a year, facilities will receive a recertification survey once every 10 years.

43. By statute, States must survey nursing homes once every 12 months and home health agencies once every 36 months. Sections 1819, 1919, and 1891 of the Social Security Act.

44. Fiscal year 2000 State Survey and Certification Budget Call Letter, July 7, 1999.

45. See 42 C.F. R., sec. 405.2136.

46. The Conditions do not give the medical director the authority to intervene in the care of a patient under another attending physician, although some facilities or corporations may give such authority. In a recent letter to a Network, HCFA stated, “Significantly, the end-stage renal disease regulations do not explicitly empower a physician-director with the authority to take independent action with respect to patients attended by other physicians.” Correspondence to Glenda Harbert, Executive Director of Network 14, from Kay Hall, Project Officer, Division Clinical Standards and Quality, Health Care Financing Administration, on November 9, 1998.

47. HCFA, State Operations Manual, Section 4009.

48. HCFA offers basic and advanced training programs for surveyors regularly throughout the year. In fact, for fiscal year 2000 HCFA has four training classes scheduled specific to dialysis facilities. HCFA’s basic training covers general topics related to the survey process in general, as well as, important technical information specifically related to dialysis facilities.

49. The most comprehensive study undertaken of medical injuries was the Harvard medical practice study. In that effort, the study team reviewed the records of about 30,000 patients hospitalized in New York State during 1984. It found that adverse events occurred in about 4 percent of the hospitalizations and negligent adverse events in about 1 percent of the cases. See Troyen A. Brennan et al, “Incidence of Adverse Events and Negligence in Hospitalized Patients,” *The New England Journal of Medicine* 324 (February 7, 1991) 6: 370-76.

A more recent study focusing on a large teaching hospital affiliated with a medical school and using a somewhat different methodology came up with even more disturbing results. It found that 17.7 percent of the 1,047 hospitalized patients reviewed received inappropriate care resulting in serious adverse events — ranging from temporary disability to death. See Lori B. Andrews et al, “An Alternative Strategy for Studying Adverse Events in Medical Care,” *The Lancet* 349 (February 1, 1997) 309-313.

50. Some States licensure laws, such as Texas, require facilities to report adverse events to the State survey agency.

51. For more information see Department of Health and Human Services, Office of Inspector General, *External Review of Hospital Quality: The Role of Accreditation*, OEI-01-97-00051, July 1999.

52. Facilities do report events involving medical devices to the Food and Drug Administration and report outbreaks of infectious diseases to the Center for Disease Control and Prevention.

53. The Network evaluation form covers the 10 topic areas such as quality improvement projects, sanctions and referrals, patient grievance, and information management. The form does not contain any objective criteria for the project officer to use but rather leaves the evaluation up to the project officer’s judgement. For example, “C.1 To the satisfaction of the project officer, the Network has developed and implemented at least one quality improvement project in option year 1, unless it was otherwise directed by HCFA.” and “C.4.I. Where appropriate to the satisfaction of the project officer, the Network has assisted patients and facilities in resolving grievances.”

54. The one Network that received two unsatisfactories involving sanctions and referrals. According to the comments attached by the project officer, this Network was not making appropriate referrals to HCFA for sanctions, was not sharing requested information with HCFA, and was inappropriately counseling a facility to withdraw from the Medicare program.

55. *Highlights from the 1999 Clinical Performance Measures Project.*

56. The HCFA name for validation surveys is Federal monitoring surveys.

57. In response to our series of reports on hospital quality oversight, HCFA has pledged to re-examine the SAQIP program and reevaluate its utility as a method for oversight for State survey agencies. In addition, HCFA intends to develop a performance measurement based system for evaluating State survey agencies. This system would provide more direct, timely feedback to States on clear criteria for performance. See the Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability*, OEI-01-97-00050, July 1999.

58. Of course, the accreditation system has a number of deficiencies of its own. We addressed these in our recent reports on hospital quality oversight. See Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability*, OEI-01-97-00050, July 1999.

59. It has been suggested that the current payment policies create disincentives for facilities and physicians to provide optimal care. Facilities receive a monthly composite rate regardless of the length or the complexity of the dialysis provided. Similarly, Medicare reimburses nephrologists at a monthly, capitated rate regardless of the complexity of the patient's condition or the frequency of visits. In addition, physicians may bill separately for inpatient hospital visits the same as other inpatient stays, which are not capitated. This often results in a financial benefit for nephrologists when their patients are hospitalized.

Others have also pointed out that the fragmented payment system makes it difficult to focus accountability. Facilities and nephrologists each receive separate payments from Medicare. Yet, each depends on the other to perform its function. The nephrologist must determine the appropriate treatment regimen and the facility must carry it out correctly in order for the patient to receive adequate care. Yet, Medicare payment policy does not hold the facility or the nephrologist accountable for working together.

In 1991, Congress asked the Institute of Medicine (IOM) to determine the impact that the reimbursement rate had had on the quality of care. Although the IOM found no demonstrative evidence that the reimbursement rate was impacting negatively on quality, it did find suggestive evidence. As a result, it recommended that "a quality assessment and assurance program should be implemented." In June of 1999, the Medicare Payment Advisory Commission recommended an increase in the composite rate in order to improve the quality of dialysis care. It further recommended that nutritional therapies for dialysis patients be under a separate payment in order to encourage facilities to provide the appropriate nutritional payments. More recently, in March 2000, the Medicare Payment Advisory Commission, again called for an increase in the composite rate, as well as to risk adjust payments for patients enrolled in Medicare+Choice.

For further discussion on this topic, see the following articles: Alan Hull, "Impact of Reimbursement Regulations on Patient Management," *American Journal of Kidney Diseases* 20 (July 1992) 1 suppl. 1: 8-11; Allen Nissenson and Richard Rettig, "Medicare's End-Stage Renal Disease Program: Current Status and Future Prospects," *Health Affairs* 18 (January/February 1999) 1: 161-179; Eli A. Friedman, "End-Stage Renal Disease Therapy: An American Success Story," *Journal of the American Medical Association* 275 (April 10, 1996) 14: 1118-1122; Renal Physicians Association correspondence to Murray K. Ross, Executive Director of the Medicare Payment Advisory Commission, May 10, 1999; Medicare Payment Advisory Commission, *Report to the Congress: Selected Medicare Issues*, June 1999, 135-148; Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2000, 129-147; Institute

of Medicine, *Kidney Failure and the Federal Government* (Washington, D.C.: National Academy Press, 1991), 17.

60. Mark R. Chassin et. al., “The Urgent Need to Improve Health Care Quality: Institute of Medicine National Roundtable on Health Care Quality,” *Journal of the American Medical Association* 280 (September 16, 1998) 11: 1000-1005.

61. In 1995 HCFA did rewrite the interpretive guidelines that offer directions to State surveyors to determine compliance with the Medicare Conditions for Coverage. The new guidelines increased the focus on patient-care processes and outcomes.

62. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards for hospitals articulate the responsibility of the governance body. The TransPacific Renal Network (#17) is actually looking to adapt the JCAHO standards for use for dialysis facilities in its region. HCFA proposed Conditions of Participation for hospitals also address this issue.

63. The June 17, 1996, draft of the Conditions for Coverage for dialysis facilities moves in this direction: “Condition: Governance. The dialysis facility is under the control of an identifiable governing body or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility, the management and provision of all dialysis services, fiscal operations, relations within the ESRD Networks, the development of policies on patient health and safety, and the quality assessment and performance improvement program. The governing body must appoint a qualified administrator who is responsible for the daily operations of the facility.”

64. The draft Conditions for dialysis facilities move toward holding the medical director more accountable by inserting, “The dialysis facility must have a medical director who is responsible for the overall delivery of patient care and outcomes.” The current Conditions of Participation for nursing homes have similar language, and concerns have been raised about how to interpret this language: “The facility must designate a physician to serve as medical director. (2) The medical director is responsible for--(i) implementation of resident care policies; and (ii) The coordination of medical care in the facility.” (42 C.F.R., sec. 483.75(i))

65. The draft Conditions for dialysis facilities address this issue, “Standard : Furnishing data and information for end-stage renal disease program. The dialysis facility furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its patient care activities and costs for administration of the program.” This may suffice as long as it is interpreted to include patient outcomes. We do not suggest that HCFA write into the Conditions specific outcomes or minimums facilities must meet. This will not allow for timely updates as scientific knowledge advances.

66. The draft Conditions for dialysis facilities also address this issue. “Condition: Quality assessment and performance improvement. The dialysis facility must develop, implement, maintain and evaluate an effective, data-drive, quality assessment and performance improvement program. The program must reflect the complexity of the dialysis facility’s organization and services (including those services provided under arrangement). The dialysis facility must take actions that result in improvements in the facility’s performance across the spectrum of care.”

67. Several national corporations collect health status and patient satisfaction data routinely from facilities nationwide. Several Networks also view patient satisfaction as an important measure of quality. For example, The ESRD Network of New England (#1) developed a patient satisfaction survey for facilities to use and the ESRD Network of Florida (#7) requires facilities to monitor patient satisfaction in its “Criteria and Standards for Facilities.”

68. HCFA currently has three projects underway to develop and implement an extensive computer system that will allow the electronic transmission of large quantities of data between facilities and Networks, and Networks and HCFA. The creation of the Renal Management Information System (REMIS) is the first project. This project will establish a new database to replace the outdated Renal Beneficiary and Utilization System (REBUS). REMIS will house all HCFA data on ESRD patients in one central database and allow for easier analysis of the data. According to HCFA’s schedule, it will be up and running sometime during the summer of 2000. The Standard Information Management Systems (SIMS) is the second project in this arena. SIMS, which is scheduled to be as of December 1999, will connect all Networks with one another and HCFA through a computer network. The third project, the Vital Information System for Improvement of Outcomes in Nephrology (VISION), will develop software to electronically link facilities with the Network to facilitate electronic data reporting. HCFA anticipates pilot testing VISION early in the year 2000, with roll out to all facilities in 2001. This entire system will electronically connect dialysis facilities to Networks, Networks to other Networks, and Networks to HCFA.

69. HCFA has funded, through the Colorado Foundation for Medical Care, the University of Michigan Kidney Epidemiology and Cost Center to produce facility-specific reports similar to the unit-specific reports generated previously by the United States Renal Data System. See www.med.umich.edu/kidney for more information.

70. HCFA has contracted with the Colorado Foundation for Medical Care to develop facility-specific reports for State survey agencies to select facilities for surveys and to use to focus their survey when on site. In the spring of 2000, HCFA plans to pilot test these reports with 8 States. HCFA has contracted with PRO-West to develop facility-specific reports for the public. These reports will be available sometime in the year 2000.

71. The Institute of Medicine called for HCFA to relate “major Conditions for Coverage to patient outcomes.” *Kidney Failure and the Federal Government*, 295. We are concerned that

the current language in draft Conditions may be too explicit. We suggest that HCFA not include in the regulations specific performance measures with specific minimums that facilities must meet. Instead, we suggest more flexible language that can allow for quicker revisions as medical knowledge progresses. The draft Conditions state: “Standard: Performance expectations. The interdisciplinary team must adjust the care plan and implementation strategies as assessment, response, and patient preference information requires. If the patient is unable to achieve the desired health outcomes, the appropriate member of the interdisciplinary team must provide an explanation. If the desired health outcome is achievable but is not being achieved, the interdisciplinary team must develop and implement an improvement program to achieve and maintain the patient’s desired level of general health...The interdisciplinary team must assist and support the patient in achieving and maintaining a desired dose of dialysis. The patient must receive at least a delivered Kt/V not less than 1.2 (single pool) or a urea reduction ratio of at least 65 percent for a majority of treatments each hemodialysis patient.”

72. For an argument in support of the release of mortality information see: John M. Newmann, “Why Should HCFA Release Center-Specific Mortality Information to Patients?” *Nephrology News and Issues*, November 1999, 13-14.

73. See HCFA’s Medicare Compare at <http://www.medicare.gov/comparison>, and Nursing Home Compare at <http://www.medicare.gov/nursing/home.asp>.

74. Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2000, p 142.

75. The Lewin Group, Inc. and Johns Hopkins University, *Facility Accreditation and Certification for ESRD Study: Evaluation of the Effectiveness of the Current End-Stage Renal Disease Survey and Certification and the Potential of Integrating Private Accreditation*, also called for a standard survey frequency and recommended it should be once every 1 or 2 years.

76. The President’s proposed budget for fiscal year 2001 for the Department of Health and Human Services calls for a 14.4 percent increase over the fiscal year 2000 appropriated budget for survey and certification activities. This funding will HCFA “to decrease the survey intervals for ESRD facilities and non-accredited hospitals from once every six years to once every three years.”p 87-88, released February 7, 2000.

77. Institute of Medicine, *To Err is Human, Building a Safer Health System* (Washington, D.C.: National Academy Press 1999).

78. The Renal Physicians Association and the Forum of ESRD Networks have created a workgroup to examine issues of patient safety in dialysis facilities.

79. Colorado publishes on the Internet facility-specific reports on complaint investigations and “occurrences” which include medical injuries. These reports provide a description of the event and the facility’s response and the State’s evaluation.
See <http://www/hfd.cdphe.state.co.us/info.asp>.